BEFORE THE INTERNATIONAL TRADE ADMINISTRATION UNITED STATES DEPARTMENT OF COMMERCE AND THE UNITED STATES INTERNATIONAL TRADE COMMISSION

) DOC Case Nos. A-351-864, A-570-184,
In the Matter of:) A-533-934, A-552-847, C-351-865,
) C-570-185, C-533-935, C-552-848,
HARD EMPTY CAPSULES FROM) and USITC Inv. Nos. 701-TA-,

BRAZIL, CHINA, INDIA, AND VIETNAM

PUBLIC VERSION

731-TA-

PROPRIETARY INFORMATION HAS BEEN REMOVED from pages 4, 6, 7, 27, 30, 31, 33-35, 44, 46-54, 58-61, 65-67, 69, 70, 74-82, 84-94; Exhibits I-1, I-3, I-6, I-8, I-14, I-15, I-21, I-30 to -34, I-46 to -51, I-57 to -60, I-68, I-69, I-78, I-81, I-84, I-87; and the Exhibit List

PETITION FOR THE IMPOSITION OF ANTIDUMPING AND COUNTERVAILING DUTIES

VOLUME I: REQUIRED INFORMATION, MATERIAL INJURY, AND THREAT OF MATERIAL INJURY

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October 24, 2024 Consultants

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I. INTRODUCTION

This Petition is filed on behalf of Lonza Greenwood LLC ("Lonza" or "Petitioner"), which represents the vast majority of U.S. production of hard empty capsules ("HECs" or the "subject merchandise"). This Petition presents information that HECs (more fully described in Section II.E below) from the Federative Republic of Brazil ("Brazil"), the People's Republic of China ("China"), the Republic of India ("India"), and the Socialist Republic of Vietnam ("Vietnam") are being sold at less than fair value ("LTFV") within the meaning of Section 731 of the Tariff Act of 1930, as amended (the "Act"), 19 U.S.C. § 1673, and have benefited from subsidies that are countervailable within the meaning of Section 701 of the Act, 19 U.S.C. § 1671. This Petition also demonstrates that the U.S. domestic industry producing HECs is materially injured, and is threatened with further material injury, by reason of the LTFV and subsidized imports of HECs from Brazil, China, India, and Vietnam, within the meaning of Sections 731 and 701 of the Act, 19 U.S.C. §§ 1673 and 1671. Petitioner therefore requests that the Department of Commerce ("Department") initiate antidumping duty ("AD") and countervailing duty ("CVD") investigations with respect to imports of HECs from Brazil, China, India, and Vietnam, and issue affirmative determinations of dumping and subsidization with respect to such imports. Further, Petitioner requests that the International Trade Commission ("Commission") institute an investigation into material injury (including the threat of material injury) to the U.S. domestic industry producing HECs by reason of such imports, and that the

Although Petitioner utilizes the terms "hard empty capsules" and "HECs" in this Petition, the subject merchandise may also be referred to in the marketplace as "empty hard capsules" or "EHCs". These terms should be considered interchangeable.

Commission issue an affirmative determination of material injury. In order to remedy the material injury that imports of HECs from Brazil, China, India, and Vietnam have caused, and threaten to cause, to the U.S. HEC industry, Petitioner ultimately requests that: (i) antidumping duties be imposed on imports of HECs from these countries in an amount equal to the amount by which the normal value ("NV") exceeds the U.S. price (*i.e.*, export price ("EP") or constructed export price ("CEP")) of the merchandise; and (ii) countervailing duties be imposed on imports of HECs from the aforementioned countries in the amount of the net countervailable subsidies that are found.

This Petition provides the information reasonably available to Petitioner and is filed in conformity with section 351.202 of the Department's regulations (19 C.F.R. § 351.202) and section 207.11 of the Commission's regulations (19 C.F.R. § 207.11).

II. REQUIRED INFORMATION

A. Identity of Petitioner — 19 C.F.R. § 351.202(b)(1)

This Petition is filed by Lonza, which—as explained further in Section II.C below—represented over 80 percent by volume of U.S. domestic production of HECs in calendar year 2023.² Lonza is a wholly-owned subsidiary of Lonza Group Ltd., a company organized and headquartered in Switzerland. As discussed in Section II.G below, in addition to Petitioner, Lonza Group Ltd. owns HEC production facilities in Belgium, China, France, India, Indonesia, Mexico, and Japan.

Petitioner's full contact information is as follows:

See Domestic Industry Support Calculations (Exhibit I-1).

Lonza Greenwood LLC 535 North Emerald Road Greenwood, SC 29646

Phone: 864-942-3851

Website: https://www.lonza.com/

Contact Person: Emilee Terry (Director, Associate General Counsel)

Phone: 618-978-9895

E-mail: emilee.terry@lonza.com

B. Description of the Domestic Industry—19 C.F.R. §§ 351.202(b)(2) and 207.11(b)(2)(ii)

Lonza is filing this Petition on behalf of the U.S. domestic industry that produces HECs. The HECs at issue in this Petition are two-piece unfilled cylindrical shells that are composed primarily of a non-toxic, biodegradable, biocompatible, and water soluble polymer material (animal-derived gelatin or plant-based polymers such as hydroxypropyl methylcellulose ("HPMC" or "hypromellose") or pullulan) and may also contain additives, colorants and/or opacifying agents, and processing agents.³ HECs are used by the pharmaceutical and nutraceutical industries.⁴ The pharmaceutical industry uses HECs as an efficient route of oral,

³ See Lonza, Technical reference file: Empty hard capsules (2023) ("Lonza, Technical reference file") at 9 (Exhibit I-2).

The pharmaceutical industry innovates and develops, produces, markets, and distributes drugs with medical (i.e., curative, preventative, risk-mitigating, and therapeutic) benefits for patients. Kline & Company, Empty Hard Capsules: United States, 2021-2022, Forecast to 2027 (Q1 2023) ("Kline, Empty Hard Capsules: United States") at 4 (Exhibit I-3). Major players in the pharmaceutical industry supply chain include active pharmaceutical ingredient ("API") manufacturers, non-active ingredient (i.e., excipient) manufacturers, packaging component and delivery mechanism manufacturers (e.g., manufacturers of HECs), finished drug developers and manufacturers (i.e., brand name, generics, and contract manufacturers), wholesalers and distributors, retail pharmacies, and hospitals. See EY, Pharma Supply Chains of the Future (2022) at 2, 8 (Exhibit I-4); see also Andrew W. Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships, Rand Corporation (2021) at vi (Exhibit I-5). The nutraceutical industry is involved in the innovation and development, manufacturing, marketing, and distribution of consumable formulations with apparent physiological effects, such as health promotion (e.g., digestion support, immune support, etc.), neurological benefits, physical performance benefits, weight loss, and disease risk mitigation effects. See Kline, Empty Hard Capsules: United States at 4 (Exhibit I-3).

nasal, inhalable, or vaginal medicine administration—*i.e.*, to deliver APIs to patients⁵ in a consumable form. The nutraceutical industry also uses HECs as a route of administration for their formulas to consumers (primarily oral). A full description of the subject merchandise—including technical characteristics, specifications, uses, production processes, and tariff classifications—is provided in Section II.E below.

As explained further in Section II.C below, in 2023, Lonza accounted for over 80 percent by volume of HEC production by the U.S. domestic industry.⁶ Lonza's HEC production facilities in the United States are located in Greenwood, South Carolina. Lonza's contact information is provided above.

Lonza is aware of only one other U.S. producer of HECs—Qualicaps, Inc. ("Qualicaps USA"). Petitioner identified all potential members of the U.S. industry through a combination of its officials' own industry member knowledge and independent market research.⁷ Qualicaps USA's HEC production facilities in the United States are located in Whitsett, North Carolina. Qualicaps USA's full contact information is as follows:

⁵ Petitioner uses the term "patients" to refer to both humans and animals that may consume pharmaceutical products.

See Domestic Industry Support Calculations (Exhibit I-1).

See Affidavit of Michael Goetter at P 3 (Exhibit I-6); see also Kline, Empty Hard Capsules: United States at 67 (Exhibit I-3)

Qualicaps, Inc.

6505 Franz Warner Parkway

Whitsett, NC 27377 Phone: 336-449-3900

Website: https://qualicaps.com/

Contact Person: Angie Roberson (President)

Phone: +1 336-449-3900

E-mail: aroberson@qualicaps.com

C. Industry Support for the Petition — 19 C.F.R. § 351.202(b)(3)

The Act requires that "the domestic producers or workers who support the petition account for at least 25 percent of the total production of the domestic like product." In addition, the Act requires that "the domestic producers or workers who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for or opposition to the petition." For this purpose, the Department typically examines data for the most recent calendar year, ¹⁰ which in the current case is 2023. Further, the Department may measure U.S. production of the domestic like product "based on either value or volume."

Petitioner's production of HECs by volume¹² in 2023 surpasses both of these thresholds for industry support established in the Act. The estimated aggregate volume of U.S. HEC production in 2023, as well as the actual or estimated volume of HEC production by each of Petitioner and Qualicaps USA in the United States, are provided in **Exhibit I-1**. As illustrated in

⁸ 19 U.S.C. §§ 1671a(c)(4)(A)(i), 1673a(c)(4)(A)(i).

^{9 19} U.S.C. §§ 1671a(c)(4)(A)(ii), 1673a(c)(4)(A)(ii).

See International Trade Administration website, *Industry Support*, https://www.trade.gov/industry-support (Exhibit I-7) ("Typically, production information should be provided for the most recently completed calendar year.").

¹¹ 19 C.F.R. § 351.203(e).

Petitioner has used U.S. production by volume for its industry support analysis because information concerning Qualicaps USA's U.S. production by value is not reasonably available to Petitioner.

As illustrated in **Exhibit I-1**, assuming that Qualicaps USA's production of HECs in 2023 totaled [8,900,000,000] units, Petitioner accounted for approximately [80.00] percent by volume of U.S. domestic production of HECs in 2023. Specifically, Petitioner produced [45,000,000,000] units of HECs, out of the approximately [53,000,000,000] units of HECs

See Domestic Industry Support Calculations (Exhibit I-1).

See Lonza, 2023 ORANGE BOOK – Hard Empty Capsules (Mar. 2024) ("Lonza, Orange Book") at 9 (Exhibit I-8).

See Lonza, Orange Book at 9 (Exhibit I-8).

See Domestic Industry Support Calculations (Exhibit I-1).

produced by the U.S. domestic industry in 2023. Even if Petitioner were to assume that Qualicaps USA's facilities had operated at 100 percent capacity utilization in 2023, Petitioner would still have accounted for [80.00] percent by volume of total U.S. domestic production of HECs in 2023. Thus, by any measure, Petitioner accounted for over 80 percent by volume of total U.S. domestic production of HECs in 2023.

Petitioner is unaware of Qualicaps USA's position on this Petition. However, to the best of Petitioner's knowledge, as noted above, Petitioner and Qualicaps USA are the only two U.S. domestic producers of HECs. Therefore, even if Qualicaps USA were to oppose this Petition, and thus the entire estimated volume of U.S. production of HECs in 2023 (approximately [53,000,000,000] units, based on the calculations above) were considered to be expressing support for or opposition to the Petition, Petitioner accounted for [90.00] percent by volume of this production. If Qualicaps USA were to oppose the Petition and its U.S. facilities had operated at 100 percent capacity utilization in 2023, Petitioner would still have accounted for [80.00] percent by volume of the portion of the U.S. industry expressing support for or opposition to the Petition.

For the foregoing reasons, Petitioner by itself accounted for over 25 percent by volume of total U.S. production of the subject merchandise in 2023 and over 50 percent by volume of the portion of the U.S. industry expressing support for or opposition to the Petition (again assuming that the only other U.S. producer, Qualicaps USA, opposes the Petition). Therefore, this Petition

See Domestic Industry Support Calculations (Exhibit I-1).

See Domestic Industry Support Calculations (Exhibit I-1).

fulfills the domestic industry support requirements under 19 U.S.C. §§ 1671a(c)(4)(A)(i) and 1673a(c)(4)(A)(i).

D. Other Import Relief Sought — 19 C.F.R. § 351.202(b)(4)

Petitioner has not previously filed for relief from imports of the subject merchandise under Section 337 of the Act (19 U.S.C. § 1337), Sections 201 or 301 of the Trade Act of 1974 (19 U.S.C. §§ 2251 or 2411), or Section 232 of the Trade Expansion Act of 1962 (19 U.S.C. § 1862).

While Petitioner has not previously filed for any such relief itself, the Office of the United States Trade Representative ("USTR") has imposed duties under Section 301 of the Trade Act of 1974 (19 U.S.C. § 2411) ("Section 301 duties") on certain imports from China after a determination that policies and practices of China related to technology transfer, intellectual property, and innovation are unreasonable or discriminatory and burden or restrict U.S. commerce.¹⁹ USTR imposed its first round of Section 301 duties in June 2018; these tariffs—which took effect for covered imports as of July 6, 2018—were set at a rate of 25 percent *ad valorem* and affected \$34 billion worth of annual imports from China.²⁰ After this first round of Section 301 duties, USTR modified the Section 301 duties on Chinese imports multiple times, to subject additional merchandise to tariffs, to modify the tariff rates applicable to certain merchandise, and to grant targeted exclusions for certain products that would otherwise be

See Notice of Determination and Request for Public Comment Concerning Proposed Determination of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 83 Fed. Reg. 14,906 (USTR Apr. 6, 2018).

See Notice of Action and Request for Public Comment Concerning Proposed Determination of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 83 Fed. Reg. 28,710 (USTR June 20, 2018).

subject to the Section 301 duties. While USTR's first and second rounds of Section 301 duties did not affect imports of the subject merchandise from China, USTR's third and fourth rounds of Section 301 duties did affect these imports. Specifically, on September 21, 2018, USTR announced that 10 percent *ad valorem* Section 301 duties would be imposed on an additional \$200 billion worth of imports from China, effective September 24, 2018 ("List 3").²¹ USTR subsequently increased the List 3 Section 301 duties to 25 percent *ad valorem* for imports that entered the United States on or after May 10, 2019 (or on or after June 15, 2019 for shipments that were exported before May 10, 2019).²² The 25 percent *ad valorem* List 3 Section 301 duties apply to, *inter alia*, imports from China under subheading 3923.90.00 of the Harmonized Tariff Schedule of the United States ("HTSUS"),²³ which is one of the subheadings under which subject merchandise may enter the United States.²⁴

Aside from subject merchandise classified under HTSUS subheading 3923.90.00, subject merchandise from China is generally subject to USTR's fourth round of Section 301 duties.

USTR announced this fourth round of Section 301 duties on August 20, 2019, and provided that those tariffs would be imposed in two tranches—with one tranche effective on September 1, 2019 ("List 4A") and another tranche effective on December 15, 2019 ("List 4B"). On

See Notice of Modifi

See Notice of Modification of Section 301 Action: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 83 Fed. Reg. 47,974 (USTR Sept. 21, 2018).

See Additional Implementing Modification to Section 301 Action: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 84 Fed. Reg. 26,930 (USTR June 10, 2019).

See Notice of Modification of Section 301 Action: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 83 Fed. Reg. 47,974, 47,987 (USTR Sept. 21, 2019).

The subheadings of the HTSUS applicable to the subject merchandise are addressed further in Section II.E.6 below.

See Notice of Modification of Section 301 Action: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 84 Fed. Reg. 43,304 (USTR Aug. 20, 2019). The List 4B Section 301 duties were suspended in December 2019 as part of the U.S.-China Phase One Agreement. See

September 1, 2019, 15 percent *ad valorem* Section 301 duties began to apply to List 4A, which includes merchandise from China within the scope of this Petition under HTSUS subheadings 2106.90.99, 3503.00.55, 9602.00.10, and 9602.00.50.²⁶ On January 22, 2020, USTR reduced the 15 percent *ad valorem* Section 301 duties on List 4A to 7.5 percent, effective February 14, 2020.²⁷ Since February 14, 2020, merchandise from China within the scope of this Petition under HTSUS subheadings 2106.90.99, 3503.00.55, 9602.00.10, and 9602.00.50 has been subject to additional 7.5 percent *ad valorem* Section 301 duties.

No Section 301 duties have been imposed on imports of HECs from Brazil, India, or Vietnam.

- E. Description of the Merchandise, Including Scope of the Investigation 19 C.F.R. § 351.202(b)(5)
 - 1. Product Description and Technical Characteristics

The merchandise subject to this Petition is hard empty capsules, or HECs. HECs are two-piece unfilled cylindrical shells composed primarily (at least 80 percent by weight, as

Notice of Modification of Section 301 Action: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 84 Fed. Reg. 69,447 (USTR Dec. 18, 2019). The List 4B Section 301 duties remain suspended as of the filing of this Petition.

See HTSUS, Chapter 99 (2024 Rev. 9) (excerpts) (Exhibit I-9). The subheadings of the HTSUS applicable to the subject merchandise are addressed further in Section II.E.6 below. Petitioner has cited to the effective version of HTSUS, Chapter 99 to demonstrate the inclusion of HTSUS subheadings 2106.90.99, 3503.00.55, 9602.00.10, and 9602.00.50 on List 4A because HTSUS subheading 2106.90.99 did not exist in 2019. HTSUS subheading 2106.90.99 appears to have existed until 2016, at which point it was removed from the HTSUS until its re-inclusion in 2022. See HTSUS, Chapter 21 (2022 Basic Edition) (excerpts) (Exhibit I-10); HTSUS, Chapter 21 (2021 Rev. 12) (excerpts) (Exhibit I-11); HTSUS, Chapter 21 (2017 Basic Edition) (excerpts) (Exhibit I-12); HTSUS, Chapter 21 (2016 Basic Edition) (excerpts) (Exhibit I-13). As a result, the August 20, 2019, Federal Register notice announcing List 4A did not include HTSUS subheading 2106.90.99. Nevertheless, the current version of HTSUS, Chapter 99 demonstrates that the List 4A Section 301 tariffs apply to this subheading.

See Notice of Modification of Section 301 Action: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 85 Fed. Reg. 3,741 (USTR Jan. 22, 2020).

discussed below) of polymer material that is non-toxic, biodegradable, biocompatible, and water soluble.

Polymer material used in HECs may be gelatin produced through the hydrolysis of animal collagen, such as animal skins, hides, and/or bones.²⁸ Cows and pigs are the most common sources of collagen for gelatin-based HECs, but fish-based gelatin is also sometimes used.²⁹

Polymer material used in HECs may also be plant-based, such as HPMC and pullulan.³⁰ HPMC is "a semisynthetic, inert, viscoelastic cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl groups."³¹ HPMC also contains "a small degree of hydroxypropyl substitution of methyl and hydroxypropyl celluloses produced from wood pulp."³² Pullulan is a natural polysaccharide (polycarbohydrate) that is "commercially produced extracellularly by the non-pathogenic and non-toxic strain" of the fungus "Aureobasidium pullulans, utilizing starch and other food grade components."³³

Minor ingredients in HECs may include additives, colorants, opacifiers, and processing aids.³⁴ Imprinting (*e.g.*, with ink or other methods) may also be added to HECs "to mark the product externally for product recognition purposes."³⁵

See Kline, Empty Hard Capsules: United States at 40 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 40 (Exhibit I-3); see also Lonza, Technical reference file at 11 (Exhibit I-2).

See Lonza, *Technical reference file* at 9 (Exhibit I-2).

See Lonza, *Technical reference file* at 9 (Exhibit I-2).

See Lonza, *Technical reference file* at 9 (Exhibit I-2).

See Lonza, *Technical reference file* at 9 (Exhibit I-2).

See Lonza, Technical reference file at 9 (Exhibit I-2).

See Lonza, Technical reference file at 9 (Exhibit I-2).

The HECs subject to this Petition are those that satisfy tests related to disintegration/dissolution in liquid biorelevant media (*e.g.*, water), such as the tests specified in Chapters 701 and 711 of the United States Pharmacopeia – National Formulary ("USP-NF"),³⁶ or equivalent tests, within 2 hours.³⁷

2. Specifications and Features

As discussed, HECs are unfilled cylindrical shells, comprised of two pieces (a cap and body). The cap and the body are each a semi-closed half cylinder, with each possessing one closed, rounded end and one open end.³⁸ The centers of both the cap and body are hollowed out. Typically, the cap and body are designed to latch together and create a hermetically sealed chamber.³⁹ To facilitate this connection between the cap and body, the open end of the cap is made slightly wider in diameter than the open end of the body. The insides of the cap and body may also contain ridges or grooves that act as an interlocking mechanism.⁴⁰ When the cap is latched onto the body, the two pieces create a sealed internal compartment that can hold substances, including powdered, liquid, viscous, semi-solid, or granular materials.

Some HECs are designed to enrobe—rather than fully encapsulate—a solid, monolithic pharmaceutical or nutraceutical product. These "enrobing caplets" still possess a cap and a body; however, the cap and body may not be designed to overlap and form a sealed unit. Rather, the cap and body of enrobing caplets may have equal diameters at their open ends and be

USP-NF Chapter 701, Disintegration (Exhibit I-14); USP-NF Chapter 711, Dissolution (Exhibit I-15).

See Lonza, Technical reference file at 163 (Exhibit I-2).

See Lonza, *Technical reference file* at 8 (Exhibit I-2).

See Kline, Empty Hard Capsules: United States at 23 (Exhibit I-3).

See Lonza, *Technical reference file* at 16 (Exhibit I-2).

designed to touch at the edges. Alternatively, the cap and body of an enrobing caplet may be applied to a solid pharmaceutical or nutraceutical product independently, in a manner that leaves a gap through which the solid product underneath is partially visible.⁴¹

HECs are produced in a variety of sizes with differing weights, lengths, diameters, and filling capacities. The typical sizing scale for HECs ranges from size 5 (smallest at approximately 11 mm closed length) to size 000 (largest at approximately 26 mm closed length). However, specialty capsules for clinical trials, pediatric and veterinary uses may be made in sizes smaller than size 5 (represented by size numbers greater than 5). A capsule of a given size may be regular, or it may deviate from the regular size by being elongated or enrobing (the latter for a type of capsule used to cover a solid product, as discussed above). HECs may also vary in terms of thickness, external coating material, and in the design of internal features on the cap and body that allow the two pieces to interlock (e.g., grooves, bumps, and ridges). In addition, HECs may be designed to facilitate either immediate or delayed release of their contents upon consumption. HECs may also be imprinted to identify the manufacturer or brand (or generic) name of the pharmaceutical or nutraceutical product contained inside.

HECs may be monochrome, multi-colored, white, black, opaque, or fully transparent.

Different color schemes or opacity levels may be used for branding and marketing purposes,

See Lonza, *Technical reference file* at 7-8 (**Exhibit I-2**). Lonza's enrobing caplets are referred to as "press fit", while other suppliers may have different names for enrobing caplets.

See, e.g., Lonza Capsugel® Sizing and Filling Capacities Guide (Exhibit I-16); Lonza Capsugel® Capsules Product Brochure (May 2022) at 12 (Exhibit I-17).

See Lonza Capsugel® Capsules Product Brochure (May 2022) at 7 (Exhibit I-17).

See Lonza Capsugel® Sizing and Filling Capacities Guide (Exhibit I-16); see also Lonza, Technical reference file at 7-8 (Exhibit I-2).

See Lonza Capsugel® Capsules Product Brochure (May 2022) at 12 (Exhibit I-17).

⁴⁶ See Lonza Capsugel® Capsules Product Brochure (May 2022) at 9, 12 (Exhibit I-17).

aesthetic purposes, and "the masking and light protection of fill material."⁴⁷ To add coloration or opacity to HECs, HEC manufacturers mix colorants or opacifying agents with the polymer base material. Titanium dioxide ("TiO₂") and calcium carbonate are common substances used to opacify HECs. ⁴⁸ While, historically, TiO₂ has been the predominant substance used to opacify HECs, regulatory requirements and consumer preferences in certain markets have resulted in less use of TiO₂ and greater use of calcium carbonate and other alternative opacifiers. ⁴⁹ Aside from calcium carbonate, alternative opacifiers may include iron oxide, ammonia caramel coloring, indigotin, and other food coloring additives. ⁵⁰ Various HEC manufacturers, including Petitioner and manufacturers of HECs in the subject countries, have developed TiO₂-free HECs that use calcium carbonate or other alternative opacifiers. ⁵¹

As noted above, the primary material in HECs is a shaped and hardened polymer, which may be animal-based gelatin (usually from pigs, cows, or fish) or a plant-based polymer such as

See Lonza, Technical reference file at 9-10 (Exhibit I-2); see also Ljiljana Palangetic, Solving the Capsule Color Challenge: Replacing Titanium Dioxide in Capsules, Lonza (June 21, 2022), https://www.lonza.com/knowledge-center/Blogs/capsule-color-challenge (Exhibit I-18) ("The shape and color of capsules can be a critical element in marketing; can aid in deterring trademark infringement; can be a safety tool to aid in preventing drug accidents, and can help with patient compliance through easier identification that leads to a better understanding of dosing.").

See Lonza, Technical reference file at 9-10 (Exhibit I-2).

See Ljiljana Palangetic, Solving the Capsule Color Challenge: Replacing Titanium Dioxide in Capsules, Lonza (June 21, 2022), https://www.lonza.com/knowledge-center/Blogs/capsule-color-challenge) (Exhibit I-18) ("France was the first to implement a national ban on the use of titanium dioxide (TiO₂) in food products based on the precautionary principle, already in January 2020. The European Commission followed suit and adopted an EU-wide ban on TiO₂ being used as an additive for all food categories, starting from August 7th 2022. Certain countries outside the European Union took the same position and also banned TiO₂ for use in food products, while others are either looking to establish their own opinion or have deemed the available data insufficient to follow the lead of France and the EU.").

See Lonza Coni-Snap® Hard Gelatin Capsules TiO₂-Free Color Guide (Exhibit I-19).

See Lonza press release, Lonza Expands its Capsugel® Capsule Offering to Include Titanium Dioxide-Free White Hard Gelatin Capsules (May 9, 2022), https://lonza.com/news/2022-05-09-10-00 (Exhibit I-20); see also Lonza, Orange Book at 19, 22 (Exhibit I-8).

HPMC and pullulan. Regardless of the polymer type used, the polymer material accounts for at least 85 percent of the dry weight of a finished HEC.⁵² As explained further below, HECs also contain water as a result of the manufacturing and storage processes. Factoring in water, the polymer material accounts for at least 80 percent of the total weight of a finished HEC.⁵³

Minor ingredients in HECs may include additives, colorants, opacifiers, and processing aids.⁵⁴ Additives—which typically account for less than 5 percent of the dry weight of an HEC (and therefore even less of the total weight of an HEC)—may be used to ensure proper formation of the polymer material into the cap and body shapes or to give the HEC certain properties.⁵⁵ For example, additives may confer upon an HEC a certain rate of disintegration/dissolution once consumed, a certain amount of plasticity, protection from oxidation and moisture, or a certain controlled-release cadence for the HEC's contents.⁵⁶

Colorants and opacifiers typically account for less than 7 percent of the dry weight of an HEC (and therefore even less of the total weight of an HEC). As described above, colorants and opacifiers are used for branding and marketing purposes, aesthetic purposes, and content masking and light protection, among other purposes.⁵⁷

See Lonza, *Technical reference file* at 9 (Exhibit I-2).

See Affidavit of Gabriel McCutcheon at P 7 (Exhibit I-21).

See Lonza, *Technical reference file* at 9 (Exhibit I-2).

See Lonza, *Technical reference file* at 9-10 (Exhibit I-2).

See Lonza, Technical reference file at 10 (Exhibit I-2); see also Ljiljana Palangetic, Solving the Capsule Color Challenge: Replacing Titanium Dioxide in Capsules, Lonza (June 21, 2022), https://www.lonza.com/knowledge-center/Blogs/capsule-color-challenge) (Exhibit I-18) ("The role of the capsule is critical. Its ingredients must be compatible with the drug product formulation or dietary ingredients it is delivering."

critical. Its ingredients must be compatible with the drug product formulation or dietary ingredients it is delivering. It must protect the fill from UV light, oxidation, and moisture. And lastly, it should control how and when the active substance/nutrient is delivered and released.").

⁵⁷ See Lonza, Technical reference file at 9-10 (Exhibit I-2).

Furthermore, processing aids are employed to facilitate the HEC manufacturing process and may appear in trace amounts (less than 1 percent by dry weight) in a finished HEC.

Common processing aids used to manufacture HECs include "mold pin release agents, wetting and glide agents ... and pH adjusters." ⁵⁸

Gelling agents are one type of processing aid that may appear in certain HECs (namely HPMC HECs). As explained below, gelling agents are added to the HPMC polymer solution during the HEC manufacturing process to ensure that the HECs settle in the proper shape and can be removed properly from the capsule production equipment.⁵⁹ Carrageenan—in combination with potassium chloride to improve polymer strength—is commonly used as a gelling agent for HPMC capsules.⁶⁰ However, it is possible to make HPMC capsules without gelling agents as well.⁶¹

In addition, as noted above, HECs may also have imprinting. Imprinting is usually accomplished using specialized ink, but other methods may also be employed. If imprinting with ink, typically, less than 150 micrograms of ink (less than 1 percent by dry weight of an HEC) would be used for a single HEC.⁶²

Finally, finished HECs also contain water left over from the manufacturing process, in which water is used to "solubilize the capsule components during formulation," 63 as well as

See Lonza, *Technical reference file* at 10 (Exhibit I-2).

⁵⁹ See Kline, Empty Hard Capsules: United States at 56 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 42, 56 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 42 (Exhibit I-3).

See Lonza, *Technical reference file* at 9 (Exhibit I-2).

See Lonza, Technical reference file at 10 (Exhibit I-2).

water content due to storage humidity.⁶⁴ Water content may vary depending on the temperature room conditions and polymer type, but it would typically account for 4-16 percent by total weight of a finished HEC at average room conditions.⁶⁵

As examples, images of certain HECs manufactured by Petitioner and the subject producers are shown in **Exhibits I-2**, **I-17**, **I-55**, **I-56**, and **I-61** through **I-67**.

3. Production Process

HEC production begins with production of the polymer (either gelatin or plant-based) used as the base material. While the manufacturing processes and equipment for the production of gelatin, HPMC, and pullulan polymers differ, the capsule manufacturing process is largely the same regardless of the polymer type used. That is, substantially similar manufacturing processes and equipment are used to produce HECs, whether they are made from gelatin, HPMC, or pullulan.⁶⁶

a. Polymer Production

i. Gelatin Production

For gelatin-based HECs, the first step in the production process is the transformation of animal collagen into gelatin. To produce gelatin, animal collagen—typically from the bones, skins, or tissue of cows, pigs, or fish (or a combination of these sources)—undergoes partial acid

See Martin Ginty, *The perfect climate for capsule storage*, Processing Magazine (Mar. 5, 2020) (**Exhibit I-22**) ("Moisture content of gelatine and HPMC capsules will vary depending on the ambient conditions as the moisture content will gradually reach equilibrium with the surrounding relative humidity level ... humidity must be considered when capsules are stored to ensure the required moisture content is maintained ...").

⁶⁵ See Affidavit of Gabriel McCutcheon at ₱ 7 (Exhibit I-21).

See Affidavit of Gabriel McCutcheon at P 9 (Exhibit I-21).

hydrolysis and/or alkaline hydrolysis.⁶⁷ This treatment process can last between one day and multiple weeks, depending on the specific animal products used as the collagen source and the particular chemical treatment process applied.⁶⁸ Specifically, the partial acid hydrolysis process (used primarily for pig products) typically takes one day, whereas the alkaline hydrolysis process (used primarily for cow products) can take multiple weeks.⁶⁹

Once the animal collagen has been transformed into gelatin through one of the aforementioned hydrolytic processes, the gelatin is extracted from any residual, unused animal matter through a sequence of warm water treatments.⁷⁰ The extracted gelatin is then fed through sophisticated, "high-performance separators" to remove any "residual traces of fat and/or insoluble particles."⁷¹ The gelatin is subsequently refiltered to remove remaining particulate contaminants, fed through a cellulose plate filtration system, and desalinated.⁷²

Next, the purified gelatin undergoes a dehydration process to make it "viscous and honey-like in consistency"; post-dehydration, the gelatin is fed through "cellulose polishing filters to remove any fine particles that may remain." The gelatin is then "heat-sterilized, ... cooled and allowed to set" into hardened "noodles." The heat sterilization process ensures that any harmful bacteria that may remain after the above processing steps are eliminated from the

See Lonza, Technical reference file at 9 (Exhibit I-2); see also Kline, Empty Hard Capsules: United States at 40 (Exhibit I-3).

See Gelita website, *Manufacture*, https://www.gelita.com/en/knowledge/gelatine/what-is-gelatine/manufacture (Exhibit I-23).

⁶⁹ See Gelita website, Manufacture (Exhibit I-23).

⁷⁰ See Gelita website, Manufacture (Exhibit I-23).

See Gelita website, *Manufacture* (Exhibit I-23).

See Gelita website, *Manufacture* (Exhibit I-23).

⁷³ See Gelita website, Manufacture (Exhibit I-23).

⁷⁴ See Gelita website, Manufacture (Exhibit I-23).

gelatin. Finally, these sterilized gelatin "noodles" may be ground down in order to be packaged for shipment to customers.⁷⁵

ii. HPMC Production

HPMC is a synthetic substance produced through the chemical reaction of an alkali cellulose with methyl chloride and propylene oxide.⁷⁶ To produce the alkali cellulose, natural plant cellulose derived from cotton or wood is treated with an alkaline solution. The viscous alkali cellulose byproduct is then partially etherified with methyl chloride, and subsequently reacted with propylene oxide.⁷⁷

iii. Pullulan Production

Pullulan production involves culturing a "non-pathogenic and nontoxigenic strain" of the fungus *Aureobasidium pullulans* in a liquid starch growth medium.⁷⁸ When cultured in this medium, *Aureobasidium pullulans* will naturally produce pullulan in the form of an "amorphous slime."⁷⁹ To make this raw substance suitable for commercial use, the pullulan is extracted from

⁷⁵ See Gelita website, Manufacture (Exhibit I-23).

See ScienceDirect website, *Hydroxypropylmethylcellulose – an overview*, https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/hydroxypropylmethylcellulose ("HPMC ScienceDirect Abstracts") (Exhibit I-24).

See HPMC ScienceDirect Abstracts (Exhibit I-24); see also Christian Muehlenfeld et al., Excipients in Pharmaceutical Additive Manufacturing: A Comprehensive Exploration of Polymeric Material Selection for Enhanced 3D Printing, 16 Pharmaceutics 1 (2024) (Exhibit I-25) ("{HPMC} is a cellulose ether prepared by reacting alkali cellulose in two steps: first, methyl chloride is added to introduce methoxy groups, followed by propylene oxide to introduce hydroxypropyl groups.").

See Organic Trade Association Letter to USDA National Organic Standards Board (Oct. 4, 2018) at 2 (Exhibit I-26).

See Singh et al., Downstream processing and structural confirmation of pullulan - A comprehensive review, 208 Int'l J. Bio. Macromolecules 553, 553 (2022), https://www.sciencedirect.com/science/article/abs/pii/S0141813022006328?via%3Dihub (Exhibit I-27).

the culture medium using particle filtration or centrifugation equipment and subsequently purified.⁸⁰

b. Capsule Production

The transformation of the polymer material into HECs involves substantially similar manufacturing processes and equipment regardless of whether the polymer used is animal- or plant-based.⁸¹ Regardless of the polymer type used, the HEC manufacturing process involves the following core steps: (1) formulation of a polymer solution in hoppers; (2) opacification or coloration; (3) capsule formation by precision-dipping mold pins into the polymer solution; (4) drying of the capsules in kilns; and (5) cutting and finishing.⁸²

Formulation of the polymer solution. The HEC production process begins with the placement of the polymer material into hoppers. Inside the hoppers, the polymer is thermally treated and mixed with filtered water to bring the solution "to an optimal temperature and viscosity." Then, after the polymer solution is allowed to rest for a period of time, a vacuum pump is used to "remove{} the air from the polymer solution."

Opacification or coloration. The next stage in the HEC production process is the opacification or coloration process. As explained in Lonza's Technical Reference Guide for its HEC products, in this stage:

See Singh et al., Downstream processing and structural confirmation of pullulan - A comprehensive review, 208 Int'l J. Bio. Macromolecules 553, 553 (2022),

https://www.sciencedirect.com/science/article/abs/pii/S0141813022006328?via%3Dihub (Exhibit I-27).

See Affidavit of Gabriel McCutcheon at P 9 (Exhibit I-21).

See Lonza, Technical reference file at 18 (Exhibit I-2).

See Lonza, Technical reference file at 18 (Exhibit I-2).

See Lonza, Technical reference file at 18 (Exhibit I-2).

{T}he polymer solution is moved to feeding tanks, where if required, an opacifier is added to obtain an opaque solution, and coloring agents or pigments to create the desired color. Following a color management step to confirm color accuracy, the feeding tank is moved to the production area where the polymer solution is transferred into dipping baths in the hard capsule machine.⁸⁵

<u>Capsule formation on mold pins</u>. During the dipping process, specialized equipment is employed to shape the colored or opacified polymer solution into capsule shells. Specifically:

Standardized stainless steel pins arranged in rows on metal bars are precision-dipped into the dipping baths containing the solution. After dipping, the bars are removed and rotated to distribute the polymer uniformly on the mold pins. The polymer is then allowed to set. Precise bar rotation, polymer viscosity and dipping rate all contribute to correct polymer distribution, resulting in a homogeneous capsule wall with an exact, specified thickness.⁸⁶

The main differences between gelatin-based HEC manufacturing and vegetable polymer-based HEC manufacturing arise at, and in connection with, the dipping stage. For gelatin-based HECs, the polymer solution is hot-dipped (*i.e.*, the gelatin is relatively hot during the dipping stage and the pin is relatively cold); for vegetable polymer-based HECs, the polymer solution may be cold-dipped (*i.e.*, the polymer is relatively cold during the dipping stage and the pin is relatively hot).⁸⁷ As a result of this difference, different thermal controls are applied to gelatin-based HECs vs. vegetable polymer-based HECs during the manufacturing process.⁸⁸

As noted above, for certain vegetable polymer-based HECs (namely HPMC capsules), gelling agents may be added to the polymer solution before the dipping process to: (1) prevent

See Lonza, Technical reference file at 18 (Exhibit I-2).

See Lonza, Technical reference file at 18 (Exhibit I-2).

See Affidavit of Gabriel McCutcheon at P 12 (Exhibit I-21).

See Affidavit of Gabriel McCutcheon at P 10 (Exhibit I-21).

the solution from sticking to the pins; and (2) help ensure that the polymer solution sets uniformly along the pin after the dipping process.⁸⁹ However, as also noted above, it is possible to make HPMC capsules without gelling agents as well.⁹⁰

<u>Drying in kilns</u>. Once the dipping process has occurred, the metal bars "carrying the pins coated with solidified gelatin, HPMC or pullulan" are then transported, via conveyor belt, though "a series of drying kilns until the moisture content is reduced to the required level."

Cutting and finishing. The shaped material is then automatically excised from the steel pins by the capsule formation equipment, formed into distinct cap and body pieces (usually designed to fit together), and cut into finished cylinders of specified lengths. The finished capsules then undergo inspections to ensure that they have been made to optimal quality, adhere to applicable regulatory requirements, and are manufactured according to customer specifications. Finally, imprinting may be applied to the finished HECs, and the HECs will be packaged for shipment.

An illustration of the HEC production process is provided at page 17 of Exhibit I-2.

4. Regulatory Requirements and Standards

Depending on the jurisdiction, HECs are considered food ingredients, excipients (*i.e.*, non-active ingredients), or even pharmaceuticals, and need to comply with applicable health and safety standards in terms of manufacturing and composition. In the United States, HECs are

⁸⁹ See Kline, Empty Hard Capsules: United States at 42, 56 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 42 (Exhibit I-3).

See Lonza, Technical reference file at 18 (Exhibit I-2).

See Lonza, *Technical reference file* at 18 (Exhibit I-2).

See Lonza, Technical reference file at 18 (Exhibit I-2).

regulated by the Food and Drug Administration ("FDA"). The FDA treats pharmaceutical HECs as excipients in finished pharmaceutical products and has approved numerous medications encapsulated in HECs made from gelatin or vegetable-based polymers. The FDA considers the quality, safety and efficacy of a candidate drug as a whole (including the HECs used) when assessing whether to approve a new drug. Further, the FDA has issued non-binding guidance on the appropriate sizes, shapes, and other physical attributes of HECs for generic versions of FDA-approved, brand name encapsulated products. The USP-NF standards also treat HECs as excipients and set forth certain non-binding manufacturing, as well as quality and performance standards, for pharmaceutical HECs. Moreover, Chapters 701 and 711 of the USP-NF set forth disintegration/dissolution tests for HECs. The United States Pharmacopeial Convention (the organization that publishes the USP-NF) is currently developing a monograph specific to HECs; however, this monograph is only in draft form at this time.

HECs made of bovine gelatin are subject to particular FDA and U.S. Department of Agriculture ("USDA") regulations. In pertinent part, FDA regulations provide that bovine gelatin in food (including dietary supplements (*i.e.*, nutraceuticals)), feed, pharmaceuticals and cosmetics is safe and permissible, as long as it has "gone through processing steps that include

Kline, Empty Hard Capsules: United States at 11 (Exhibit I-3).

See FDA website, Inactive Ingredient Search for Approved Drug Products, https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm (accessed July 29, 2024) (Exhibit I-28).

See FDA Center for Drug Eval. & Res., Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules: Guidance for Industry (Oct. 2022) (Exhibit I-29).

See USP-NF Chapter 1059, Excipient Performance (Exhibit I-30); USP-NF Chapter 1078, Good Manufacturing Practices for Bulk Pharmaceutical Excipients (Exhibit I-31).

See USP-NF Chapter 701, Disintegration (Exhibit I-14); see also USP-NF Chapter 711, Dissolution (Exhibit I-15).

filtration and sterilization or an equivalent process in terms of infectivity reduction."⁹⁹ These requirements are intended to minimize the risk of bovine spongiform encephalopathy ("BSE")/transmissible spongiform encephalopathy ("TSE") in gelatin for human consumption. ¹⁰⁰ USDA also administers regulations specific to imports of bone-derived gelatin, to minimize the risk that such imports will contain material presenting a risk of BSE/TSE. ¹⁰¹

Certain specific standards also apply to the materials used in the production of HECs. In particular, gelatin used in HECs intended for pharmaceutical use should comply with the USP-NF standards for gelatin; ¹⁰² and gelatin used in HECs intended for nutraceutical use should comply with the Food Chemicals Codex ("FCC") standards for "food grade" gelatin. ¹⁰³ HPMC used in both pharmaceutical and nutraceutical applications should comply with the USP-NF standards for HPMC (there are no separate FCC standards for HPMC). ¹⁰⁴

Finally, if a change of HEC supplier results in a pharmaceutical manufacturer using HECs with new specifications or a new composition, that change will be subject to FDA approval.¹⁰⁵ FDA policies also provide that a drug applicant that changes its supplier of gelatin HECs post-approval of its drug—but keeps the composition and specifications of its HECs constant—should submit information about that new supplier in an annual report.¹⁰⁶ Such

⁹⁹ 21 C.F.R. § 189.5(a).

See Use of Materials Derived From Cattle in Human Food and Cosmetics, 81 Fed. Reg. 14,718 (FDA Mar. 18, 2016).

¹⁰¹ 9 C.F.R. § 94.23.

See USP-NF, Food-Grade Gelatin (Exhibit I-32).

See Food Chemical Codex, Gelatin (Exhibit I-33).

See USF-NF, Hypromellose (Exhibit I-34). "Hypromellose" is another term for HPMC.

See FDA Office of Pharmaceutical Quality, Change in Hard Gelatin Capsule Shell Supplier, MAPP 5016.6 (Feb. 21, 2023) (Exhibit I-35).

See FDA Office of Pharmaceutical Quality, Change in Hard Gelatin Capsule Shell Supplier, MAPP 5016.6 (Feb. 21, 2023) (Exhibit I-35).

information should include: (1) the new HEC supplier's name and address; (2) a certification from the new supplier "that the gelatin used conforms with {USP-NF} specifications for gelatin"; (3) a BSE/TSE certification for the new supplier's gelatin; and (4) the new HEC's specifications. These requirements make it more costly for a pharmaceutical manufacturer to switch gelatin HEC suppliers.

5. Uses

HECs are used by the pharmaceutical and nutraceutical industries as a mechanism of delivering formulations to patients/consumers. Virtually all of the customers that purchase HECs from HEC producers are pharmaceuticals and nutraceuticals manufacturers. These manufacturers, in turn, fill HECs with their formulations and deliver the filled HECs to patients/consumers as finished pharmaceutical and nutraceutical products. HECs can facilitate various forms of consumption—oral administration, vaginal administration, inhalation, or simple opening for pouring into containers or sprinkling into food or beverages. 109

HECs offer many benefits to pharmaceutical and nutraceutical manufacturers, and to those that consume formulations packaged within HECs. For example, HECs "promot{e} ease of swallowing, mask{} unpleasant taste or odor {of their contents}, hid{e} or improv{e} {the} visual appearance of fill material, facilitate{e} blinding in clinical studies{,} ... present{} a unique appearance as they can be produced in a wide range of colors, sizes and imprinting

See FDA Office of Pharmaceutical Quality, Change in Hard Gelatin Capsule Shell Supplier, MAPP 5016.6 (Feb. 21, 2023) at 2 (Exhibit I-35).

Petitioner is aware of very minor HEC volumes sold to U.S. consumers for "self-formulation" on e-commerce platforms.

See Lonza, Technical reference file at 8 (Exhibit I-2).

possibilities," and mediate the release time of their contents. Because HECs can be marked to identify the manufacturer of their contents, HECs can also promote brand awareness for the finished capsule manufacturers. Typically, pharmaceutical manufacturers utilize imprinted HECs while nutraceutical manufacturers do not. 111

6. Current Tariff Classification

Merchandise subject to these investigations is classifiable under the following subheadings of Chapter 96 of the HTSUS:¹¹²

- 9602.00.1040 ("Worked vegetable or mineral carving material and articles of these materials; molded or carved articles of wax, of stearin, of natural gums or natural resins, of modeling pastes, and other molded or carved articles, not elsewhere specified or included; worked, unhardened gelatin (except gelatin of heading 3503) and articles of unhardened gelatin: Worked unhardened gelatin and articles thereof: Unfilled gelatin capsules"); or
- 9602.00.5010 ("Worked vegetable or mineral carving material and articles of these materials; molded or carved articles of wax, of stearin, of natural gums or natural resins, of modeling pastes, and other molded or carved articles, not elsewhere specified or included; worked, unhardened gelatin (except gelatin of heading 3503) and articles of unhardened gelatin: Other: Unfilled vegetable capsules").

That said, pursuant to NY Customs Ruling K89023 dated September 3, 2004,¹¹³ some importers may import gelatin HECs under HTSUS subheading 3503.00.5510, which reads as follows:

• 3503.00.5510 ("Gelatin (including gelatin in rectangular (including square) sheets, whether or not surface-worked or colored) and gelatin derivatives;

See Lonza, *Technical reference file* at 8 (Exhibit I-2).

See Affidavit of Michael Goetter at P 14 (Exhibit I-6).

See HTSUS, Chapter 96 (2024 Rev. 9) (excerpts) (Exhibit I-36).

See CBP Ruling Letter No. K89023 (Sept. 3, 2004) (Exhibit I-37).

isinglass; other glues of animal origin, excluding casein glues of heading 3501: Other Edible gelatin"). 114

However, several other customs rulings indicate that the correct classification for gelatin HECs is 9602.00.1040 because gelatin HECs are "unhardened" for customs purposes. 115

In addition, pursuant to NY Customs Ruling M80491 dated March 22, 2006,¹¹⁶ some importers import HPMC HECs under HTSUS subheading 3923.90.0080 and pullulan HECs under HTSUS subheading 2106.90.9998, which read as follows:¹¹⁷

- 3923.90.0080 ("Articles for the conveyance or packing of goods, of plastics; stoppers, lids, caps and other closures, of plastics: Other: Other"); or
- 2106.90.9998 ("Food preparations not elsewhere specified or included: Other: Other").

During the Commission's January 2021 to June 2024 period of investigation ("POI"),

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on publicly available import statistics and market intelligence, Petitioner believes that the vast majority of *subject* imports of vegetable polymer-based HECs are currently imported under

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See HTSUS, Chapter 35 (2024 Rev. 9) (Exhibit I-38).

See CBP Ruling Letter No. D89279 (Nov. 16, 1999) (Exhibit I-39); CBP Ruling Letter No. D80818 (Nov. 24, 1998) (Exhibit I-40); CBP Ruling Letter No. 811937 (June 29, 1995) (Exhibit I-41); CBP Ruling Letter No. 804031 (Nov. 28, 1994) (Exhibit I-42).

See CBP Ruling Letter No. M80491 (Mar. 22, 2006) (Exhibit I-43).

See HTSUS, Chapter 21 (2024 Rev. 9) (excerpts) (Exhibit I-44); HTSUS, Chapter 39 (2024 Rev. 9) (excerpts) (Exhibit I-45).

HTSUS subheading 9602.00.5010, which was introduced just a few months prior to NY Customs Ruling M80491, through the release of the 2006 Basic Edition of the HTSUS. 118 Moreover, Petitioner believes that the vast majority of subject (and non-subject) imports of gelatin HECs are currently imported under HTSUS subheading 9602.00.1040. Further, Petitioner believes that HTSUS subheadings 9602.00.1040 and 9602.00.5010 do not include non-subject merchandise. Therefore, HTSUS subheadings 9602.00.1040 and 9602.00.5010 should be considered largely coextensive with the scope. Petitioner provides all of the relevant HTSUS subheadings for convenience and for customs purposes. Petitioner emphasizes that the written description of the scope in Section II.E.7 below is dispositive.

7. Proposed Scope Language

The following language describes the imported merchandise from Brazil, China, India, and Vietnam that is proposed to be within the scope of this Petition:

The merchandise subject to the scope of this investigation is hard empty capsules (HECs), which are unfilled cylindrical shells composed of at least 80 percent by weight of a non-toxic, biodegradable, biocompatible, and water soluble polymer, and may also contain water, additives, opacifiers, colorants, and processing aids. HECs may also be imprinted or otherwise decorated with markings.

The most common polymer materials in HECs are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan. However, HECs may also be made of other non-toxic, biodegradable, biocompatible, and water soluble polymer materials.

HECs are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one

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See HTSUS, Chapter 96 (2005 Basic Edition) (excerpts) (Exhibit I-88); HTSUS, Chapter 96 (2006 Basic Edition) (excerpts) (Exhibit I-89).

closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

HECs are covered by the scope of this investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

HECs are also covered by the scope of this investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of HECs are covered by the scope of this investigation regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Products that do not disintegrate/dissolve in a liquid biorelevant medium (e.g., water) under tests specified in the United States Pharmacopeia — National Formulary (USP-NF), or equivalent disintegration/dissolution tests, within 2 hours are not covered by the scope of this investigation.

HECs are classifiable under subheadings 9602.00.1040 or 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, gelatin HECs may be imported under HTSUS subheading 3503.00.5510; HPMC HECs may be imported under HTSUS subheading 3923.90.0080; and pullulan HECs may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by this investigation is dispositive.

F. Countries of Exportation — 19 C.F.R. § 351.202(b)(6)

The HECs that are the subject of this Petition are produced in and exported from Brazil, China, India, and Vietnam. Petitioner is not aware of the particular export practices of producers and exporters in the subject countries, but notes that subject merchandise produced in Brazil, China, India, or Vietnam remains subject to this proceeding regardless of the country from which it is exported to the United States.

G. Producers and Exporters of Subject Merchandise — 19 C.F.R. §§ 351.202(b)(7)(i)(A) and (ii)(A)

As noted, Petitioner believes that the producers/exporters identified in **Exhibit I-46** have sold the subject merchandise at LTFV in the United States, as demonstrated in Volumes II, III, IV, and V of this Petition. In addition, as further explained in Volumes VI, VII, VIII, and IX of this Petition, Petitioner believes that the producers/exporters identified in **Exhibit I-46** have also benefitted from countervailable subsidies.

As noted in Section II.A, Petitioner has affiliated HEC producers in Belgium, China, France, India, Indonesia, Mexico, and Japan. Petitioner does not believe that its affiliates in the subject countries—*i.e.*, China and India—have exported the subject merchandise to the United

For a discussion of foreign suppliers of HECs to the U.S. market, *see* Affidavit of Michael Goetter at **PP** 3-10 (**Exhibit I-6**).

States at dumped and subsidized prices during the POI. Nonetheless, should the Department and Commission require, the contact information for Petitioner's Chinese and Indian affiliates is as follows:

Suzhou Capsugel ® Ltd.

Address: No. 369 Suhong Middle Road, Suzhou Industrial Park, Suzhou 215027,

Jiangsu, China

Telephone: +86 512 6258 5188

E-mail: legalchina.nansha@lonza.com

Website: https://www.lonza.com/about-us/our-locatio31uzhouhou-china

Capsugel Healthcare Private Ltd.

Address: 21, Joniawas, Dharuhera, Distt. Rewari, Harya-a - 123110, India

Telephone: +91 (124) 605 2900 **E-mail:** contact.india@lonza.com

Website: https://www.lonza.com/about-us/our-locations/rewari-india

In regard to Petitioner's imports of HECs from its affiliates, in most cases, Petitioner imports small, occasional volumes of HECs from its affiliates to meet specific customer needs. However, Petitioner imports more meaningful volumes of HECs from Mexico that are produced by its Mexican affiliate—Capsugel de Mexico S. de R.L. de CV ("Capsugel de Mexico")—

pursuant to [] with Capsugel de Mexico. 121 [

 $1.^{122}$

Petitioner supplies some of the HECs produced by Capsugel de Mexico to the U.S. market.¹²³
The remainder of the HECs that Petitioner imports from Mexico are re-exported to customers or

] (Exhibit I-47).

See Affidavit of Michael Goetter at ₱ 5 (Exhibit I-6).

See Affidavit of Michael Goetter at 7 5 (Exhibit I-6).

¹²² See [

See Affidavit of Michael Goetter at \(\bigvee 5 \) (Exhibit I-6).

affiliates of Petitioner in Mexico and other countries. 124

H. Calculation of U.S. Price and Normal Value — 19 C.F.R. § 351.202(b)(7)(i)(B)

Factual information pertaining to the calculation of U.S. price (EP or CEP) and NV for producers/exporters of HECs from Brazil, China, India, and Vietnam is provided in Volumes II, III, IV, and V of this Petition, respectively.

I. Identification of China and Vietnam as Non-Market Economies — 19 C.F.R. § 351.202(b)(7)(i)(C)

China and Vietnam are treated as non-market economies ("NMEs") for antidumping purposes. As noted above, Volumes III and V of this Petition contain the information necessary to substantiate LTFV allegations and factual information relevant to China and Vietnam, respectively.

J. Subsidy Allegations — 19 C.F.R. § 351.202(b)(7)(ii)(B)

Factual information pertaining to countervailable subsidies provided to producers/exporters of HECs in Brazil, China, India, and Vietnam is provided in Volumes VI, VII, VIII, and IV of this Petition, respectively.

K. Volume and Value of Subject Imports — 19 C.F.R. § 351.202(b)(8)

Estimates of the volume and value of U.S. imports of HECs from Brazil, China, India, and Vietnam are presented at **Exhibit I-48** for calendar years 2021, 2022, 2023, and January through June 2023 ("H1 2023") and January through June 2024 ("H1 2024"). The source for these data is U.S. Census Bureau ("U.S. Census") import data downloaded from the U.S. Census

See Affidavit of Michael Goetter at \$\mathbb{P}\$ 5 (Exhibit I-6).

website and the Commission's DataWeb for imports for consumption under HTSUS subheadings 9602.00.1040 and 9602.00.5010. For value, Petitioner used the Landed Duty Paid ("LDP") values for imported merchandise under HTSUS subheadings 9602.00.1040 and 9602.00.5010, as reported in the Commission's DataWeb.

As described in Section II.E.6 above, certain HECs also enter the United States under HTSUS subheadings 3503.00.5510, 3923.90.0080, and 2106.90.9998, which are basket subcategories for various forms of gelatin, plastic conveyance mechanisms, and miscellaneous food preparations, respectively. Because these HTSUS subheadings are large basket categories, they contain significant quantities of non-subject merchandise, and it is not possible to glean meaningful information about the volume and value of subject merchandise imported under these subheadings. Petitioner believes that the inclusion of volume and value data under HTSUS subheadings 3503.00.5510, 3923.90.0080, and 2106.90.9998 would, therefore, significantly distort its datasets for subject imports. As described in Section II.E.6 above, despite I, Petitioner believes that the vast majority of subject merchandise—by volume and value—enters the United States under HTSUS subheadings 9602.00.1040 and 9602.00.5010. For these reasons, Petitioner uses the official U.S. Census import statistics for HTSUS subheadings 9602.00.1040 and 9602.00.5010 as a proxy for the volume and value of imports of the subject merchandise, and does not include import volume and value data under HTSUS subheadings 3503.00.5510, 3923.90.0080, and 2106.90.9998 in its calculations. The import volume and value data under HTSUS subheadings 9602.00.1040 and

9602.00.5010 are the best import data for the subject merchandise reasonably available to Petitioner for purposes of this Petition.

However, as described in Sections III.D and III.H.2 below, to provide the Commission with the most accurate picture of total U.S. HEC imports for purposes of its negligibility and market share calculations, Petitioner has supplemented the official U.S. Census import statistics for HTSUS subheadings 9602.00.1040 and 9602.00.5010 with [

J. Petitioner provides a detailed description of its method to supplement official U.S. import data in this manner in Section III.D and in **Exhibits I-50**, **I-68**, and **I-84**.

L. Importers of the Subject Merchandise — 19 C.F.R. §§ 351.202(b)(9) and 207.11(b)(2)(iii)

Based on information reasonably available to Petitioner, **Exhibit I-49** contains the names, addresses and other contact information for companies that may be U.S. importers of subject merchandise. Petitioner believes, however, that there may be additional U.S. importers of subject HECs that Petitioner has been unable to identify. Accordingly, Petitioner requests that the Department and the Commission obtain this information from U.S. Customs and Border Protection ("CBP"), because Petitioner does not have access to this information.

M. Material Injury, Threat of Material Injury, and Causation — 19 C.F.R. § 351.202(b)(10)

Petitioner establishes that the domestic HEC industry is materially injured and threatened with further material injury by reason of subject imports from Brazil, China, India, and Vietnam in Section III below.

III. THE DOMESTIC INDUSTRY IS MATERIALLY INJURED, AND IS THREATENED WITH FURTHER MATERIAL INJURY, BY REASON OF UNFAIRLY TRADED IMPORTS FROM BRAZIL, CHINA, INDIA, AND VIETNAM

A. Introduction

Imports of HECs from Brazil, China, India, and Vietnam have caused material injury to the U.S. domestic industry and threaten the domestic industry with further material injury.

Between 2021 and 2023, subject imports gained [*] percentage points of U.S. market share while U.S. producers lost U.S. market share. Comparisons between H1 2023 and H1 2024 show that subject imports are flooding the U.S. market and capturing additional market share from U.S. producers. Specifically, between H1 2023 and H1 2024, subject imports captured an additional [*] percentage points in U.S. market share. Meanwhile, U.S. producers lost [*] percentage points in U.S. market share between H1 2023 and H1 2024. During the January 2021 to June 2024 POI, subject imports substantially undersold the domestic like product (by margins of up to [40.00] percent), and, as a result, caused the U.S. industry to lose significant sales and revenues. Subject imports also depressed and suppressed U.S. prices during the POI. The negative effect of subject imports on the capacity utilization, production

48).

See Market Share Calculations (**Exhibit I-50**).

See Market Share Calculations (Exhibit I-50); see also Volume and Value of Subject Imports (Exhibit I-

See Lost Sales and Lost Revenues (Exhibit I-69); see also Underselling Analysis (Exhibit I-51).

volumes, U.S. shipments and market share, employment, financial performance, and domestic investments of the U.S. industry has been profound.

Given these factors, subject imports also threaten the U.S. domestic industry with further material injury. Because its trade, operational, and financial performance was adversely affected by the subject imports, the U.S. HEC industry is vulnerable to further injury by the subject imports. The extraordinary increase in U.S. market share held by subject imports, especially during the latter part of the POI, demonstrates that the subject producers can further increase their presence in the U.S. market at the expense of U.S. producers. The HEC industries in the subject countries already have substantial unused capacity to expand production, and many producers in these countries are aggressively expanding their capacity even further as a result of recent investments. Moreover, U.S. demand for HECs is expected to rise in the coming years. In other words, producers in the subject countries have strong incentives to continue exporting significant volumes of underpriced HECs to the United States. These factors all indicate that subject imports will continue to damage the already injured and vulnerable domestic HEC industry.

B. The Domestic Like Product Is Coextensive with the Scope — 19 U.S.C. § 1677(10) and 19 C.F.R. § 207.11(b)(2)(i)

The Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation" ¹²⁸ In defining the domestic like product, the Commission applies the statutory standard of "like" or

¹⁹ U.S.C. § 1677(10).

"most similar in characteristics and uses" on a case-by-case basis. 129 The Commission generally considers a number of factors, including: (1) physical characteristics and uses;

- (2) interchangeability; (3) channels of distribution; (4) customer and producer perceptions;
- (5) the use of common manufacturing facilities, production processes, and production employees; and (6) where appropriate, price.¹³⁰ As the Commission has explained in numerous cases, "{n}o single factor is dispositive, and the Commission may consider other factors it deems relevant based on the facts of a particular investigation. The Commission looks for clear dividing lines among possible like products and generally disregards minor variations."¹³¹

For the reasons discussed below, the Commission should define a single domestic like product that is coextensive with the definition of the subject merchandise—*i.e.*, a single domestic like product consisting of all HECs. The Commission should not expand the domestic like product to include other dosage forms—such as tablets, soft-shell capsules ("softgels"), and gummies.

1. Physical Characteristics and Uses

All HECs sold in the U.S. market possess the same basic physical characteristics and uses. All HECs are two-piece unfilled cylindrical shells that possess a cap piece and a body piece, and are made primarily of a non-toxic, biodegradable, biocompatible, and water soluble

See, e.g., Cleo Inc. v. United States, 501 F.3d 1219, 1299 (Fed. Cir. 2007); NEC Corp. v. Department of Commerce, 36 F. Supp. 2d 380, 383 (Ct. Int'l Trade 1998); Nippon Steel Corp. v. United States, 19 CIT 450, 455 (Ct. Int'l Trade 1995).

See Nippon Steel Corp. v. United States, 19 CIT 450, 455 fn. 4 (Ct. Int'l Trade 1995); Timken Co. v. United States, 913 F. Supp. 580, 584 (Ct. Int'l Trade 1996).

See, e.g., Non-Refillable Steel Cylinders from India, Inv. Nos. 701-TA-689 and 731-TA-1618 (Final), USITC Pub. 5509 (May 2024) at 4-5; see also Nippon Steel Corp. v. United States, 19 CIT 450, 455 (Ct. Int'l Trade 1995).

polymer. In all HECs, the cap and body pieces are hollowed out such that they each possess one open end and one closed, rounded end. Regardless of the polymer used, the polymer material accounts for at least 80 percent by weight of an HEC.¹³² All HECs serve the same end use, as mechanisms to deliver pharmaceutical and nutraceutical formulations to patients/consumers, whether human or animal.

While other dosage forms often serve the same end uses as HECs, they possess fundamentally different physicochemical characteristics. For example, tablets are neither two-piece, unfilled, nor uniformly composed of polymers. Rather, tablets are a solid dosage form composed primarily of a compacted particulate mixture that is first blended for uniformity of excipients and actives and subsequently compressed into the final tablet formulation. Tablets also generally contain a higher number of excipients than HECs. ¹³³ While some of the same raw ingredients used in certain HECs may be used in tablets (*e.g.*, HPMC), these ingredients have different functions and often appear in different physical form in tablets than they do in HECs. ¹³⁴ Softgels are not two-piece and contain considerable concentrations of plasticizers (*e.g.*, glycerin or sorbitol) that HECs do not contain. ¹³⁵ Furthermore, softgels cannot be shipped/sold empty like HECs. Gummies are neither two-piece nor unfilled, and—unlike HECs—they often contain sugar in addition to the gelling agent (*e.g.*, gelatin, pectin). ¹³⁶ While also utilizing gelatin as a

See Affidavit of Gabriel McCutcheon at ₱ 7 (Exhibit I-21).

See Kline, Empty Hard Capsules: United States at 22 (Exhibit I-3) (referencing additional excipients for tablets such as coatings, printings, and encapsulations).

For example, HPMC is used as a primary structural material for HECs, but is blended with other ingredients and used as a binder, disintegrant, or coating substance in tablets. *See* HPMC ScienceDirect Abstracts (Exhibit I-24).

See Kline, Empty Hard Capsules: United States at 26 (Exhibit I-3).

See Affidavit of Michael Goetter at ₽ 12 (Exhibit I-6).

primary ingredient, gummies are a solid mass containing a suspended or dissolved active ingredient in the matrix. Other dosage forms are also of different consistencies and textures than HECs. The following graphic illustrates how HECs differ from principal other dosage forms.



2. Manufacturing Facilities, Production Processes and Employees

The production of all HECs involves substantially similar equipment and the same basic manufacturing process. As explained in Section II.E.3 above, regardless of the polymer type used, and regardless of whether the HECs will be sold to the pharmaceutical or nutraceutical

See Affidavit of Gabriel McCutcheon at ₱ 9 (Exhibit I-21).

segment of the market, the HEC manufacturing process involves the following core steps:

(1) formulation of a polymer solution in hoppers; (2) opacification or coloration of the polymer solution in feeding tanks; (3) capsule formation by precision-dipping mold pins into the polymer solution; (4) drying the capsules in kilns; and (5) cutting and finishing. To that end, all HEC manufacturing involves the following machines: (1) hoppers; (2) a vacuum pump to remove air from the polymer solution in the hoppers; (3) feeding tanks; (4) a capsule formation machine with standardized mold pins assembled on moving metal bars and a mechanism to dip the pins into the polymer solution; (5) drying kilns; (6) equipment to excise the hardened capsules from the pins; and (7) equipment to cut the excised capsules into the cap and body pieces. 139

Because the production of all HECs involves substantially similar equipment and the same core steps, manufacturing workers require substantially similar training and skills to produce HECs of any kind. ¹⁴⁰ Indeed, at Petitioner's Greenwood, South Carolina facility, the same workers handle production of HECs of all polymer types and for all market segments. ¹⁴¹

By contrast, the manufacturing equipment and processes for other dosage forms are substantially different from the equipment and processes used to produce HECs. Indeed, HEC manufacturing equipment cannot be used to produce other dosage forms. Tablet production involves a drastically different process than HEC production. Unlike HEC production, tablet production typically involves a blending process for particulate materials, followed closely by a

See Lonza, *Technical reference file* at 18 (Exhibit I-2).

See Lonza, Technical reference file at 18 (Exhibit I-2).

See Affidavit of Gabriel McCutcheon at P 18 (Exhibit I-21).

See Affidavit of Gabriel McCutcheon at P 18 (Exhibit I-21).

See Affidavit of Michael Goetter at P 13 (Exhibit I-6).

compression process by which this blend of granular or powdered materials is compacted into a tablet. A Conversely, core steps in the HEC manufacturing process are inapplicable to tablets; tablet manufacturing does not involve precision-dipping mold pins into a polymer solution. As Michael Goetter—Lonza Group Ltd.'s Vice President ("VP") and Regional Business Unit Head — Americas for Capsules and Health Ingredients—explains in his affidavit: "softgel production requires specialized manufacturing equipment and technical expertise" that is not applicable to the production of HECs. Moreover, unlike HECs, softgels are filled with formulations at the same time they are produced. Gummy manufacturing is also substantially different from HEC manufacturing. In pertinent part, gummies are produced by filling molds with a heated gummy solution and then feeding those filled molds through cooling equipment. In other words, unlike HEC production, gummy production does not involve a pin-dipping process. Other dosage forms also utilize various different production processes.

3. Channels of Distribution

HECs are sold through the same channels of distribution regardless of the polymer type used in the HECs and regardless of the market segment to which the HECs are being sold.¹⁴⁷ Specifically, as Mr. Goetter attests in his affidavit, in the United States, "HECs of all types are primarily sold directly to end-users" (*i.e.*, pharmaceutical and nutraceutical manufacturers,

See Qualicaps Corporate Brochure (2023) at 19 (Exhibit I-52); see also Kline, Empty Hard Capsules: United States at 25 (Exhibit I-3).

See Affidavit of Michael Goetter at P 13 (Exhibit I-6).

See Kline, *Empty Hard Capsules: United States* at 26 (Exhibit I-3).

See CapsPlus Technologies website, *How Vitamin Gummies are Manufactured* (Apr. 21, 2021), https://capplustech.com/2021/04/21/how-vitamin-gummies-are-manufactured/ (Exhibit I-53).

See Affidavit of Michael Goetter at PP 15-17 (Exhibit I-6).

including contract manufacturing organizations ("CMOs") manufacturing on their behalf, as well as generics producers). In some cases, HECs in the U.S. market are sold through intermediate distributors. Virtually all HECs are filled with pharmaceutical or nutraceutical formulations before they reach patients/consumers. This typically occurs at the purchaser of HECs, *i.e.*, regional or multi-national brand owners in the nutraceutical industry or marketing authorization holders (including innovators, generics and over-the-counter ("OTC") medicines producers) in the pharmaceutical industry, or their CMOs.

By contrast, other dosage forms such as tablets, softgels, and gummies are not sold in an unfilled form to nutraceutical and pharmaceutical manufacturers. Rather, these dosage forms are created by the nutraceutical and pharmaceutical manufacturers themselves. In other words, when producing finished products in the tablet, softgel, or gummy form, nutraceutical and pharmaceutical manufacturers do not purchase analogous "empty shells" for their products from third parties, as they do in connection with finished products in the capsule form. Rather, tablets, softgels, and gummies are both formed and filled at the same stage of manufacturing.

4. Interchangeability

There is substantial interchangeability across HECs. Regardless of their polymer type, dimensions, weight, color, opacity or transparency, filling capacity, or other features, all HECs are designed to contain formulations and to be consumed by patients/consumers. Pharmaceutical

See Affidavit of Michael Goetter at P 15 (Exhibit I-6).

See Affidavit of Michael Goetter at P 16 (Exhibit I-6). In addition, as Mr. Goetter attests, "a very small portion of commercial HEC sales in the U.S. market are retail sales, including sales through e-commerce platforms." *Id.*

Petitioner is aware of very minor HEC volumes sold to U.S. consumers for "self-formulation" on e-commerce platforms.

and nutraceutical manufacturers may purchase HECs with different feature combinations, but will always use HECs of any kind in the same manner—to encapsulate their formulations for consumption by patients/consumers.

While different features may make certain HECs more easily consumable by patients/consumers (*e.g.*, smaller-sized HECs, or HECs that can be opened to sprinkle a powdered substance onto food), HECs exist on a continuum of consumability. Similarly, different features may make HECs disintegrate/dissolve and release their contents more or less quickly upon consumption; make HECs better protect their ingredients from ambient moisture, light, or oxygen; or make HECs capable of containing ingredients of different consistencies. However, such features also exist on a continuum, and there are too many permutations of HECs with different feature combinations to draw clear dividing lines between HECs.

HECs are not interchangeable with other products. As noted above, there is no analog for HECs in the production of other oral dosage forms, because other oral dosage forms do not have shells made separately from their fillings. As Mr. Goetter explains in his affidavit:

HECs are a single, unique product type. HECs are empty shells that are manufactured separately from the pharmaceutical and nutraceutical formulations with which they are ultimately filled to produce filled hard capsules. Further, HEC manufacturing and capsule filling are entirely separate processes ... there is no direct substitute for HECs. Rather, the shells of other dosage forms are manufactured together with the filling (as is the case with softgels), or the dosage form lacks a shell that is distinct from its filling (as is the case with tablets and gummies). ¹⁵³

See Affidavit of Michael Goetter at P 21 (Exhibit I-6).

See Lonza, *Technical reference file* at 28-31 (Exhibit I-2); see also Affidavit of Michael Goetter at P 21 (Exhibit I-6).

See Affidavit of Michael Goetter at P 11 (Exhibit I-6).

Moreover, other dosage forms have low interchangeability with filled hard capsules because the HECs used to make filled hard capsules can possess certain characteristics that these other dosage forms inherently cannot. For example, without special additives, tablets are not resilient against external elements such as moisture or oxygen. Further, tablets are only used for solid formulations; softgels are generally not used for solid, granular, or powdered formulations; and gummies are only used for gelatinous (and sometimes, liquid) formulations. By contrast, HECs can contain solid, liquid, semisolid, viscous, granular, multi-phase, and powdered contents. HECs may also contain other dosage forms as a secondary payload, such as a miniature tablet, capsule, beadlet, or suspension not possible in other dosage forms.

5. Producer and Customer Perceptions

Producers of HECs view all HECs as a single product type that is distinct from other dosage forms. The fact that HEC producers view their capsule models in this manner is evident in the fact that they create marketing materials covering their full portfolio of HECs (or the vast majority of their HEC portfolios). Further, as Mr. Goetter states in his affidavit, "many HEC producers are distinct companies exclusively focused on HEC manufacturing and

See Kline, Empty Hard Capsules: United States at 22 (Exhibit I-3); see also CapsCanada website, Oral Dosage Forms Comparison: What You Need to Know When Choosing Between Pills, Tablets, Capsules, Softgels, Chewables, and Gummies (June 12, 2024), https://blog.capscanada.com/oral-dosage-forms-comparison-what-you-need-to-know-when-choosing-between-pills-tablets-capsules-softgels-chewables-and-gummies (Exhibit I-54) ("Tablets are not an appropriate dosage format for heat-sensitive or low-melting-point formulations or for large-dose actives.").

See Kline, Empty Hard Capsules: United States at 26 (Exhibit I-3) ([

See Affidavit of Michael Goetter at PP 21-22 (Exhibit I-6).

See, e.g., Lonza, *Technical reference file* (Exhibit I-2); see also ACG Capsules Range Brochure (2017) (Exhibit I-55); Suheung Capsule Embo Caps® Brochure (Exhibit I-56).

sales."¹⁵⁸ Companies that produce and distribute HECs as well as other dosage forms and/or excipients produce HECs and these other products on different manufacturing lines, and more often at different facilities altogether.

Market analysts also view HECs as a single product type with characteristics that exist along a continuum. For example, Kline & Company ("Kline") prepares consolidated market reports (available through subscription) that cover all HECs and describe products other than HECs—such as tablets, softgels, and gummies—as distinct dosage forms in competition with HECs. Furthermore, regulators and standards bodies (*e.g.*, the FDA and the institution that publishes the USP-NF, the United States Pharmacopeial Convention) view capsules as a unique dosage form and HECs themselves as a distinct category of excipient. ¹⁶⁰

In addition, the direct purchasers of HECs—pharmaceutical and nutraceutical manufacturers—view HECs as a single product type. These purchasers view HECs as a discrete dosage form that is distinct from other dosage forms. ¹⁶¹ Further, purchasers view HECs with different characteristics (*e.g.*, different polymer types, dimensions, weights, filling capacities,

See Affidavit of Michael Goetter at ₽ 13 (Exhibit I-6).

See Kline, Empty Hard Capsules: United States (Exhibit I-3); see also Kline & Company, Empty Hard Capsules: Brazil Business Analysis and Opportunities; Base Years 2019, 2020; Forecasts to 2025 (Feb. 2021) ("Kline, Empty Hard Capsules: Brazil") (Exhibit I-57); Kline & Company, Empty Hard Capsules: India; Base Year 2021-2022; Forecasts to 2027 (Apr. 2023) ("Kline, Empty Hard Capsules: India") (Exhibit I-58); Kline & Company, Empty Hard Capsules: China Business Analysis and Opportunities; Base Years 2021, 2022; Forecasts to 2027 (Apr. 2023) ("Kline, Empty Hard Capsules: China") (Exhibit I-59); Kline & Company, Empty Hard Capsules: Vietnam Business Analysis and Opportunities; 2019-2020; Forecast to 2025 (Q1 2021) ("Kline, Empty Hard Capsules: Vietnam") (Exhibit I-60).

See FDA website, Inactive Ingredient Search for Approved Drug Products, https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm (accessed September 30, 2024) (Exhibit I-28); see also USP-NF Chapter 1059, Excipient Performance (Exhibit I-30); USP-NF Chapter 1078, Good Manufacturing Practices for Bulk Pharmaceutical Excipients (Exhibit I-31).

See Affidavit of Michael Goetter at P 22 (Exhibit I-6).

etc.) as existing on a continuum of functionality and suitability for their needs. ¹⁶² Direct purchasers may perceive HECs with certain characteristics as better suiting a particular pharmaceutical or nutraceutical formulation, but—as illustrated by Petitioner's and the subject producers' marketing materials—there are numerous combinations of characteristics that might suit a manufacturer's needs for a certain formulation. ¹⁶³ In other words, various characteristics can be "mixed and matched" to give a certain batch of HECs particular aesthetic properties and functionalities. ¹⁶⁴ There are too many permutations of feature combinations to draw clear dividing lines between HECs. However, clear dividing lines can be drawn between HECs and other dosage forms, because other dosage forms have structural features, compositions, textures, and consistencies that are fundamentally different from those of HECs.

Finally, ultimate consumers (*i.e.*, those who ingest drugs and nutraceuticals) view HECs as distinct from other dosage forms. For example, Kline notes that [

].¹⁶⁵ As Kline states, [

See Affidavit of Michael Goetter at PP 21-22 (Exhibit I-6).

See, e.g., Lonza, Technical reference file (Exhibit I-2); Healsee Capsules website, Titanium Dioxide Free Vegetable Capsule, https://www.capshealsee.com/tio2-free-hpmc/titanium-dioxide-free-vegetable-capsule.html (Exhibit I-61); Healsee Capsules, Vegetable Capsules Product Brochure (Exhibit I-62); BioCaps website, Gelatin Capsules, https://biocaps.net/portfolio/yegetable-capsules-bio-v/ (Exhibit I-63); BioCaps website, Vegetable Capsules Bio-V, https://www.healthcaps.com/Capsules/pharma (Exhibit I-65); ACG Product Profiles Brochure (Exhibit I-66); HealthCaps India website, Products: Empty Capsules, https://www.healthcapsindia.com/products-empty-capsules (Exhibit I-67); Suheung Capsule Embo Caps® Brochure (Exhibit I-56); ACG Capsules Range Brochure (2017) (Exhibit I-55).

See Affidavit of Michael Goetter at P 21 (Exhibit I-6).

See Kline, Empty Hard Capsules: United States at 21 (Exhibit I-3).

1.¹⁶⁶ Similarly, consumers

who prefer to chew a drug or nutraceutical product would prefer tablets or gummies over HECs.

The fact that consumers may seek different dosage forms depending on such preferences illustrates that consumers do not perceive HECs as comparable with tablets, softgels, gummies, and other dosage forms.

6. Price

While prices for HECs differ depending on their characteristics (*e.g.*, polymer type, the presence or absence of gelling agents, etc.) and market segment (*e.g.*, whether the HECs are sold to the pharmaceutical or nutraceutical segments), prices of all types of HECs follow similar trends. HEC prices follow similar trends because of the substantially similar manufacturing processes involved, comparable cost structures across HEC products, and overlapping supply and demand conditions that apply to the various types of HEC products.

By contrast, the pricing landscape for other dosage forms differs from that of HECs. For example, tablets are cheaper than HECs because the costs of tablet production are lower than the costs of HEC production. Softgels, on the other hand, are generally more expensive than HECs because of their specialized and higher-cost production process and typically greater usage of raw material (*e.g.* gelatin). 168

See Kline, Empty Hard Capsules: United States at 21 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 21-22 (Exhibit I-3) (noting that tablets []).

See CapsCanada website, Oral Dosage Forms Comparison: What You Need to Know When Choosing Between Pills, Tablets, Capsules, Softgels, Chewables, and Gummies (June 12, 2024), https://blog.capscanada.com/oral-dosage-forms-comparison-what-you-need-to-know-when-choosing-between-pills-

7. Conclusion

For all of these reasons, the Commission should find the domestic like product to be all HECs, coextensive with the scope of the subject merchandise. The Commission should not expand the domestic like product to include other dosage forms.

C. Domestic Industry — 19 U.S.C. § 1677(4)(A)

The Act defines the relevant domestic industry as "the producers as a whole of a domestic like product, or those producers whose collective output of a domestic like product constitutes a major proportion of the total domestic production of the product." Based on the domestic like product defined above, the domestic industry consists of the U.S. producers of HECs. As discussed in Section II.B above, the two U.S. producers of HECs are Petitioner and Qualicaps USA.

As explained in Section II.C, Petitioner accounted for at least [80.00] percent—and potentially [90.00] percent—of the volume of U.S. production of the domestic like product in 2023. Given that Petitioner's data provides the Commission with significant coverage of the performance of the domestic industry, those data support affirmative determinations of material injury and threat of material injury to the U.S. HEC industry.

<u>tablets-capsules-softgels-chewables-and-gummies</u> (Exhibit I-54) ("Softgel manufacturing, which is very specialized, is considerably more expensive than manufacturing pharmaceutical or nutraceutical products in tablets, caplets or capsules. A component of these higher costs is gelatin wastage, which equals to up to 40% of the web size.").

¹⁹ U.S.C. § 1677(4)(A).

D. Negligibility — 19 U.S.C. § 1677(24)

The Act provides that imports from a subject country of merchandise corresponding to a domestic like product are negligible if they account for less than 3 percent of the volume of all such merchandise imported into the United States in the most recent 12-month period for which data are available preceding the filing of the petition, or 4 percent in the case of developing countries in a CVD investigation. None of the four subject countries are considered developing countries by the U.S. Trade Representative, and hence the relevant negligibility threshold in this case for purposes of both the AD and CVD investigations for all four subject countries is 3 percent.

As shown in **Exhibit I-68**, the most recent 12-month period for which import data are available is September 2023 through August 2024. Petitioner has calculated total U.S. imports of HECs during this period by using U.S. Census data for imports for consumption under HTSUS subheadings 9602.00.1040 and 9602.00.5010,¹⁷² supplemented by [

]. Petitioner has supplemented the U.S. Census data with [
] in two ways. First, Petitioner has replaced the official U.S. Census data for imports
for consumption from [
] under HTSUS subheading 9602.00.1040 with [

¹⁹ U.S.C. §§ 1671b(a), 1673b(a), 1677(24)(A)(i), 1677(24)(B).

See Designations of Developing and Least-Developed Countries Under the Countervailing Duty Law, 85 Fed. Reg. 7613 (USTR Feb. 10, 2020).

See Sections II.E.6 and II.K above for a discussion of why these HTSUS subheadings are an appropriate proxy for subject merchandise imports.

See Affidavit of Ty James Corallo at ₱ 3 (Exhibit I-84).

1.¹⁷⁴ To

the best of Petitioner's knowledge, Petitioner [

]. 175 In the course of preparing this Petition, Petitioner discovered

that some [

].¹⁷⁶ Specifically, some [

1.177 As a result, some of the U.S. Census data for imports under subheading

9602.00.1040— [] —appear to be

understated.¹⁷⁸ Because [

], Petitioner has used its [

for imports under subheading 9602.00.1040 from [

I instead of the official U.S.

Census data.¹⁷⁹

Second, for the reasons explained in Section II.E.6 above, Petitioner has [

] to the figures for total U.S. imports under HTSUS

See Affidavit of Ty James Corallo at ₱ 5 (Exhibit I-84).

See Affidavit of Ty James Corallo at ₱ 5 (Exhibit I-84).

See Affidavit of Ty James Corallo at 4 (Exhibit I-84).

See Affidavit of Ty James Corallo at P 4 (Exhibit I-84).

See Affidavit of Ty James Corallo at P 4 (Exhibit I-84).

See Affidavit of Ty James Corallo at PP 4-5 (Exhibit I-84).

subheadings 9602.00.1040 and $9602.005010.^{180}$ By using [] as the source for these figures, Petitioner has [].

1. Subject Imports from China, India, and Vietnam Are Not Negligible

From September 2023 through August 2024, imports of HECs from China, India, and Vietnam accounted for the following percentages of total U.S. imports of HECs by volume:

[15.00] percent for imports from China; [20.00] percent for imports from India; and [15.00] percent for imports from Vietnam. Therefore, imports of HECs from each of China, India, Vietnam clearly surpass the negligibility standard for both the AD and CVD investigations.

2. Subject Imports from Brazil Are Also Likely Not Negligible

First, Petitioner has no reliable method by which to estimate imports of HECs from Brazil that may be imported under HTSUS subheadings 2106.90.9998, 3923.90.0080, 3503.00.5510. To the extent any HECs are imported from Brazil under these subheadings, data

See Affidavit of Ty James Corallo at P 6 (Exhibit I-84).

See Affidavit of Ty James Corallo at P 4 (Exhibit I-84).

See Negligibility Calculations (Exhibit I-68).

See Negligibility Calculations (Exhibit I-68).

only reflecting imports for consumption from Brazil under HTSUS subheadings 9602.00.1040 and 9602.00.5010 would underestimate total U.S. imports of the subject merchandise from Brazil.

Second, U.S. importers of HECs from Brazil may have [

]. To the extent that such discrepancies exist, the U.S. Census data for import volumes from Brazil under HTSUS subheadings 9602.00.1040 and 9602.00.5010 would again be understated. The average unit values ("AUVs") for imports for consumption from Brazil under HTSUS subheading 9602.00.5010 suggests that for vegetable polymer-based HECs, such discrepancies may indeed exist. AUVs for imports for consumption from Brazil under HTSUS subheading 9602.00.5010 were over \$3,000.00 in some months (and even over \$5,000.00 in one month) between September 2023 and August 2024. These AUVs deviate to an extreme extent from the prices seen in the U.S. market for vegetable polymer-based HECs. These AUVs are not reflective in the slightest of HEC pricing and suggest that quantities for imports from Brazil under HTSUS subheading 9602.00.5010 may be misreported.

Petitioner also notes that when [] are removed from the calculation of total U.S. imports of HECs, Brazil accounted for [*] percent of total U.S. imports of HECs between September 2023 and August 2024. Should the Commission deem it appropriate to remove [] I from the calculation of total U.S.

See AUVs for Subject Imports from Brazil (Exhibit I-85).

See Negligibility Calculations (Exhibit I-68).

imports of HECs for purposes of its negligibility analysis, subject imports from Brazil surpass the negligibility threshold.

3. Even If Subject Imports from Brazil Are Negligible, Such Imports Should be Considered for Purposes of Determining Threat of Material Injury

The Act provides that, "for purposes of determining threat of material injury", the Commission shall not treat otherwise-negligible imports as negligible if the Commission "determines that there is a potential that {such} imports ... will imminently account for more than 3 percent of the volume of all such merchandise imported into the United States." For the many reasons explained below, even if subject imports from Brazil are negligible within the meaning of the Act, such imports have the potential to imminently exceed 3 percent of total U.S. imports of HECs and therefore these investigations should proceed with respect to Brazil.

First, over the period of September 2023 to August 2024, subject imports from Brazil accounted for [*] percent of total U.S. imports of HECs pursuant to Petitioner's analysis discussed above—just [*] percentage points less than 3 percent. 187

Second, in the most recent month for which data are available (August 2024), subject imports from Brazil *did* account for over 3 percent of total U.S. imports of HECs (specifically, * | percent). Indeed, in four months between September 2023 and August 2024, subject imports from Brazil accounted for over 3 percent of total U.S. imports of HECs. Monthly data for imports from Brazil under HTSUS subheadings 9602.00.1040 and 9602.00.5010 show that,

¹⁸⁶ 19 U.S.C. § 1677(24)(A)(iv).

See Negligibility Calculations (Exhibit I-68).

See Negligibility Calculations (Exhibit I-68).

See Negligibility Calculations (Exhibit I-68).

over the past 12 months, HEC imports from Brazil were particularly high in the last quarter of the 2023 calendar year. This trend, combined with the fact that imports from Brazil under HTSUS subheadings 9602.00.1040 and 9602.00.5010 were rising in July and August 2024, 190 suggests that the Brazilian subject producers are conducting robust sales campaigns in the latter half of the year. Therefore, it is likely that HEC imports from Brazil will continue rising over the next few months and will remain over 3 percent of total U.S. imports.

Third, as explained further in Section III.I.2.b below, the Brazilian subject producers have significant unused production capacity. Assessments conducted by Petitioner based on available market intelligence indicate that, in 2022, the HEC manufacturing equipment at ACG do Brazil S.A. ("ACG Brazil") operated at just [60] percent capacity.¹⁹¹ Kline also reported in 2021 that [

Fourth, the Brazilian subject producers have strong interests in exporting HECs across the Americas, including to the United States. For example, in August 2024, ACG Brazil's General Sales Manager Raphael Sideris highlighted the plant's exports to the United States as a significant reason for the plant's strong performance in July 2024. With U.S. demand for HECs expected to grow in the coming years, Brazilian subject producers have every incentive to increase their exports to the United States. In fact, as demonstrated by Exhibit I-69, Petitioner

See Negligibility Calculations (Exhibit I-68).

See Lonza, Orange Book at 10 (Exhibit I-8).

See Kline, Empty Hard Capsules: Brazil at 67 (Exhibit I-57).

See Fabio Reis, ACG Reaches the reord of 2 billion capsules produced and sold in the last month, PFarma.com.br (Aug. 20, 2024), Exhibit I-86).

See Lonza Annual Report (2023) at 54 (Exhibit I-70).

has faced significant competition from Brazilian imports resulting in lost sales and lost revenues. Moreover, ACG Brazil is also affiliated with ACG Associated Capsules Pvt. Ltd. ("ACG India"), which together are part of the ACG Group ("ACG"), 195 and if these investigations result in AD/CVD orders with respect to India but not Brazil, ACG will have every incentive to shift its exports of HECs to the United States from India to Brazil.

E. Proposed Pricing Products — 19 C.F.R. § 207.11(b)(2)(iv)

Pursuant to section 207.11(b)(2)(iv) of the Commission's regulations, Petitioner recommends that the Commission collect pricing data on the four types of HECs described below.

- **Product 1** Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.
- **Product 2** Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), NOT imprinted, and sold in per 1,000 unit increments.
- **Product 3** Hard empty hydroxypropyl methylcellulose ("HPMC") capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.
- **Product 4** Hard empty hydroxypropyl methylcellulose ("HPMC") capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), NOT imprinted, and sold in per 1,000 unit increments.

Petitioner believes that these pricing products are representative of the prevalent domestically-produced and imported HECs sold in the U.S. market, and will provide the

See Affidavit of Michael Goetter at P 7 (Exhibit I-6).

Commission with robust and appropriate pricing data for the purpose of making price comparisons. Gelatin capsules are the most prevalent type of HECs present in the U.S. market and tend to be less expensive than non-gelatin capsules. Moreover, among non-gelatin capsules, HPMC capsules are most prevalent in the U.S. market. PMC capsules are most prevalent in the U.S. market.

Petitioner has distinguished between imprinted HECs and non-imprinted HECs because the existence or absence of imprinting is a physical characteristic that serves as a strong indicator for the market segment to which HECs are sold. HECs sold to pharmaceutical end-users are typically imprinted, whereas HECs sold to nutraceutical end-users are typically not imprinted. HECs sold to the nutraceutical market tend to be less expensive than HECs sold to the pharmaceutical market, because the latter tend to be required to meet higher quality standards and comply with stricter regulatory requirements faced by pharmaceutical manufacturers (*e.g.*, FDA requirements for drug developers related to changes in their gelatin HEC supplier). Petitioner believes that a distinction based on the existence or absence of imprinting will largely capture these price differences while offering a clear physical characteristic for parties reporting pricing data in response to the Commission's U.S. Producer and U.S. Importer questionnaires.

Petitioner has selected pricing products focused on HECs of sizes between 00 to 3 (whether regular, elongated, or enrobing²⁰⁰) because such sizes account for the more common

See Kline, Empty Hard Capsules: United States at 40-44, 47-48 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 56-62 (Exhibit I-3).

See Affidavit of Michael Goetter at P 14 (Exhibit I-6).

See Kline, Empty Hard Capsules: United States at 47-48 (Exhibit I-3).

As discussed above, enrobing capsules are ones that are used to cover a solid product.

HEC sales in the U.S. market, while other sizes tend to be for specialized purposes (*e.g.*, clinical trials).

Petitioner has also indicated that the pricing products should be for products sold in per 1,000 unit increments. All suppliers in the U.S. HEC market generally sell their products in prices per 1,000 unit increments. While different suppliers may ship their products in different quantities and different size bags, pricing is not affected by bag size or quantities within a bag and remains in price per 1,000 unit increments. For these reasons, Petitioner believes the above four pricing products will best enable the Commission to conduct its pricing analysis.

Pricing data from domestic producers and U.S. importers should be collected using the Commission's standard methodology, *i.e.*, <u>f.o.b.</u>, <u>U.S. point of shipment</u>, and should not include U.S. inland transportation costs. While U.S. producers and foreign subject producers of HECs "typically provide price quotations to U.S. customers on a delivered basis", ²⁰¹ Petitioner believes that the collection of pricing data on f.o.b., U.S. point of shipment terms will allow the Commission to conduct optimally precise price comparisons. Values should reflect the *final net* amount paid to reporting firms (*i.e.*, should be net of all deductions for discounts or rebates). Further, pricing for these products should be presented on a per 1,000 units quantity basis to match the general practice in the U.S. HECs market as described above, and volumes should be reported on the basis of quantity in 1,000 units irrespective of size.

See Affidavit of Michael Goetter at P 20 (Exhibit I-6).

F. Lost Sales and Lost Revenue Allegations — 19 C.F.R. § 207.11(b)(2)(v)

Subject producers have used unfair, artificially-low pricing to take significant sales and revenues from Petitioner in recent years.²⁰² Petitioner identifies the main purchasers from which it lost sales or revenues as a result of subject imports—and describes the instances of lost sales and revenues involving said purchasers—in **Exhibit I-69**. As illustrated in **Exhibit I-69**, Petitioner has lost a substantial number of sales, many of which were [

], to underpriced subject imports.²⁰³ Petitioner has also been forced to lower its prices for HECs in the U.S. market to avoid losing certain sales to subject imports. As Mr. Goetter explains in his affidavit (and as is illustrated by the allegations in **Exhibit I-69**), "{i}n some instances, Lonza has been forced to lower prices by as much as [] percent to keep sales."²⁰⁴

] to subject imports priced between [25.0] and [28.0] percent lower than Petitioner's original offered price. ²⁰⁶

See Lost Sales and Lost Revenues (Exhibit I-69). Pursuant to 19 C.F.R. § 207.11(b)(2)(v), Petitioner has provided information on lost sales and lost revenue that is reasonably available to it. This information is also being submitted electronically as required by the Commission's regulations.

See Lost Sales and Lost Revenues (Exhibit I-69); see also Affidavit of Michael Goetter at P 28 (Exhibit I-69).

See Affidavit of Michael Goetter at P 29 (Exhibit I-6).

See Affidavit of Michael Goetter at 28 (Exhibit I-6).

See Lost Sales and Lost Revenues (Exhibit I-69).

In addition, Petitioner's lost sales include instances where customers to whom Petitioner has provided [

].207 [

].²⁰⁸ In other

words, Petitioner has lost many "sales of HECs [

], based simply on price.²⁰⁹

In fact, the U.S. market for HECs is so price-sensitive that Petitioner has been forced to forego charging customers for certain ancillary support services in order to keep sales. Petitioner

J.²¹⁰ However, Petitioner generally cannot charge for these services and materials, because adding such charges would "jeopardize {Lonza's} U.S. customer relationships and endanger Lonza's sales."²¹¹ Simply put, HECs are so price-sensitive, and

See Affidavit of Michael Goetter at \$\mathbb{P}\$ 30 (Exhibit I-6).

See Affidavit of Michael Goetter at P 30 (Exhibit I-6).

See Affidavit of Michael Goetter at 30 (Exhibit I-6).

See Affidavit of Michael Goetter at \$\mathbb{P}\$ 31 (Exhibit I-6).

See Affidavit of Michael Goetter at P 31 (Exhibit I-6).

competition from subject imports is so aggressive, that Petitioner cannot reap the benefit of distinguished, high-quality services that it traditionally provides to its customers.

G. Conditions of Competition — 19 U.S.C. § 1677(7)(C)

The Commission should consider the following conditions of competition in the U.S. HEC market when analyzing whether there is material injury by reason of subject imports.

1. HEC Producers from All of the Subject Countries Compete in the U.S. Market on the Basis of Price

The HECs produced by the U.S. industry and by producers from Brazil, China, India, and Vietnam (and other countries) are a "highly fungible commodity product" in the U.S. market.²¹² Price is the primary factor affecting pharmaceutical and nutraceutical manufacturers' HEC purchasing decisions in almost all instances.²¹³ Indeed, a 2023 report by Kline describing the conditions of competition in the U.S. market for HECs (the "2023 Kline Report") highlights the

Kline Report also recognizes that, in light of the high level of product fungibility, [

], and that [

] in the HEC market.²¹⁵ Even more telling, the 2023 Kline Report emphasizes that Chinese and Indian HEC suppliers sell products in the United States that are [

See Affidavit of Michael Goetter at P 23 (Exhibit I-6).

See Affidavit of Michael Goetter at 23 (Exhibit I-6).

See Kline, Empty Hard Capsules: United States at 48 (Exhibit I-3).

Kline, Empty Hard Capsules: United States at 48 (Exhibit I-3).

 $1.^{216}$

Further, as mentioned in Section III.F above, the U.S. market for HECs is so pricesensitive that Petitioner has been forced to forego charging customers for certain ancillary support services in order to keep sales.

2. Demand Conditions

As noted above, the primary consumers of HECs are pharmaceutical and nutraceutical manufacturers, including brand-name manufacturers, contract manufacturers, and generics producers. The market for HECs therefore involves two main segments: the pharmaceutical segment and the nutraceutical segment. The nutraceutical segment of the market is roughly 3.5 times larger than the pharmaceutical segment of the market.²¹⁷ According to the 2023 Kline Report, the vast majority of demand in the pharmaceutical segment is for gelatin HECs, but demand for vegetable polymer-based HECs is present (and growing) in this segment as well.²¹⁸ Gelatin-based and vegetable polymer-based HECs each have a robust presence in the nutraceutical segment of the U.S. market, but the majority of demand ([60.0] percent in 2022) in this segment is for vegetable polymer-based HECs.²¹⁹ Growing U.S. demand for vegetable polymer-based HECs is supported by health-conscious consumers switching to vegan and

See Kline, Empty Hard Capsules: United States at 72 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 5, 94 (Exhibit I-3).

See Kline, *Empty Hard Capsules: United States* at 56 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 61-62 (Exhibit I-3).

vegetarian lifestyles.²²⁰ Total U.S. demand for HECs is expected to grow by 2 to 3 percent annually in the coming years.²²¹

a. Pharmaceutical Segment

U.S. demand for pharmaceutical HECs is, first and foremost, tied to the health of the U.S. pharmaceutical innovation and manufacturing base. The United States is home to some of the world's largest and most innovative pharmaceutical companies. These companies are the immediate purchasers of pharmaceutical HECs, who use this product for clinical trials and finished product packaging. U.S. generics manufacturers also require HECs to package their formulations. As such, robust U.S. pharmaceutical R&D and manufacturing (including generics manufacturing) supports U.S. demand for HECs. 223

Since the United States is also one of the largest markets in the world for finished pharmaceutical products, the health of the U.S. pharmaceutical innovation and manufacturing base (and thus, the industry's demand for HECs) is connected to U.S. demand for finished pharmaceuticals. Demand for pharmaceuticals in the United States is complex and multi-dimensional, as aggregate pharmaceutical demand depends on specific demand for therapeutics to treat thousands of different indications. To that end, demand for pharmaceuticals in the United States—and thus, demand for pharmaceutical HECs in the United States—is impacted by the dynamics of the following factors, among others: (1) health trends across the U.S. population (including the prevalence of contagious diseases and certain chronic conditions); (2) willingness

See Kline, Empty Hard Capsules: United States at 56, 61-62 (Exhibit I-3).

See Lonza Annual Report (2023) at 54 (Exhibit I-70).

See Kline, Empty Hard Capsules: United States at 82 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 87, 95 (Exhibit I-3).

of U.S. patients to visit the hospital and accept prescription treatments; (3) the age distribution of the U.S. population; (4) drug prices; and (5) government healthcare and tax policies that either promote or disincentivize pharmaceutical consumption (*e.g.*, policies that promote employer-provided health insurance, policies affecting patient reimbursement for drug costs, etc.).²²⁴

Demand for pharmaceutical HECs is also affected by manufacturer and downstream consumer (*i.e.*, patient) demand for competing dosage forms, such as tablets, softgels, or gummies.²²⁵

b. Nutraceutical Segment

U.S. demand for nutraceutical HECs is tied to U.S. demand for products such as dietary supplements and vitamins, mineral supplements, and probiotics.²²⁶ U.S. demand for these products is growing over the long term, because the U.S. population is aging and consumers are increasingly focused on proactive healthcare, including but not limited to: immune system health, gut and digestive health, neurological health, and weight management.²²⁷

3. Supply Conditions

U.S.-produced HECs and the subject merchandise compete in both the pharmaceutical and nutraceutical segments of the U.S. market.²²⁸ Moreover, in both segments of the U.S.

See Kline, Empty Hard Capsules: United States at 87 (Exhibit I-3); see also Congressional Budget Office, Research and Development in the Pharmaceutical Industry (April 2021) (Exhibit I-71) ("The federal government ... increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance.").

See Kline, Empty Hard Capsules: United States at 88 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 89 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 89, 94 (Exhibit I-3); see also PwC, Vitamins & Dietary Supplements Market Trends – Overview (2020) (Exhibit I-72) ("The key product influencing growth in North America is probiotic supplements. Probiotic supplements are increasingly positioned as beneficial not only for digestion but also for immunity, allowing for broader use scenarios for prevention. The US is expected to see high growth in probiotic supplements, fish oils / omega fatty acids, and protein supplements. Demand for probiotics stems from greater consumer awareness of digestive issues and food sensitivities.").

See Kline, Empty Hard Capsules: United States at 69-71 (Exhibit I-3).

market, producers from the subject countries have expanded their shipments of aggressively lowpriced product to capture additional market share since 2021.

a. Pharmaceutical Segment

The top three suppliers of pharmaceutical HECs in the United States are Petitioner,

Qualicaps USA and its foreign affiliates (collectively, "Qualicaps"), and ACG.²²⁹ Petitioner
supplies pharmaceutical HECs to the U.S. market from its Greenwood, South Carolina,
manufacturing facility. In addition, Petitioner sometimes supplies U.S. pharmaceutical
customers with HECs imported from Petitioner's foreign affiliates.²³⁰ Qualicaps USA supplies
pharmaceutical HECs to the U.S. market from its Whitsett, North Carolina, manufacturing
facility. Qualicaps USA also has HEC manufacturing affiliates in Brazil, Japan, Romania, and
Spain.²³¹ It is Petitioner's understanding that Qualicaps USA supplies the U.S. market with
imported pharmaceutical HECs produced by its Brazilian affiliate—Genix Indústria
Farmacêutica Ltda. ("Qualicaps Brazil").²³² Petitioner does not have insight into Qualicaps
USA's possible supply to the U.S. market of pharmaceutical HECs produced by its affiliates in
Japan, Romania, or Spain.

ACG has affiliated HEC manufacturing facilities in Brazil, Croatia, India and Thailand.²³³ It is Petitioner's understanding that ACG supplies the U.S. market with imported

See Kline, Empty Hard Capsules: United States at 67 (Exhibit I-3).

See Affidavit of Michael Goetter at P 5 (Exhibit I-6).

See Qualicaps Corporate Brochure (2023) at 7 (Exhibit I-52).

See Affidavit of Michael Goetter at P 6 (Exhibit I-6).

See ACG Corporate Brochure (2021) at 14 (Exhibit I-73); see also CareEdge Ratings, ACG Associated Capsules Private Limited (Dec. 7, 2023) at 1-2, 5 (Exhibit I-74); Lonza, Orange Book at 20 (Exhibit I-8).

pharmaceutical HECs produced by its Croatian, Brazilian, and Indian facilities.²³⁴ Petitioner does not have insight into ACG's possible supply to the U.S. market of pharmaceutical HECs produced by its facilities in Thailand. Since 2021, ACG has [

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Other suppliers active in the U.S. market for pharmaceutical HECs include Suheung (a South Korea-based producer with HEC manufacturing facilities in South Korea and Vietnam), Jiangsu Lefan Capsule Co. Ltd. ("LefanCaps"), Healthcaps LLC ("Healthcaps"), Farmacapsulas S.A. / CapsCanada Corporation ("Farmacapsulas / CapsCanada"), Shanxi Guangsheng Capsule Co., Ltd. ("GS Capsules"), Shanxi Jicheng Biotechnology Co., Ltd. ("Bright Caps"), Zhejiang Lujian Capsule Co., Ltd ("LJCaps"), and Bio Caps, among other Indian and Chinese suppliers.²³⁶

b. Nutraceutical Segment

The top three suppliers of nutraceutical HECs in the United States are Petitioner, ACG, and Suheung. Petitioner supplies nutraceutical HECs produced at its Greenwood, South Carolina, manufacturing facility to the U.S. market. Petitioner also supplies nutraceutical HECs produced by its Mexican affiliate—Capsugel de Mexico—to the U.S. market. In addition, Petitioner sometimes supplies U.S. nutraceutical customers with HECs imported from Petitioner's other foreign affiliates as well.²³⁷ It is Petitioner's understanding that ACG supplies

See Kline, Empty Hard Capsules: Brazil at 67 (Exhibit I-57) (

^{]);} see also 9th Nutri India Summit: Past Speakers,
https://web.archive.org/web/20181004145216/http://www.nutraindiasummit.in/nutra 2014/speakers directory indv
<a href="https://web.archive.org/web/20181004145216/http://www.nutraindiasummit.in/nutra 2014/speakers directory indv
<a href="https://web.archive.org/web/20181004145216/https://www.nutraindiasummit.in/nutra 2014/speakers directory indv
<a href="https://web/archive.org/web/20181004145216/https://www.nutraindiasummit.in/nutra 2014/speakers directory indv
<a href="https://web/archive.org/we

See Kline, Empty Hard Capsules: United States at 70 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 69 (Exhibit I-3); Affidavit of Michael Goetter at PP 8-10 (Exhibit I-6).

See Affidavit of Michael Goetter at P 5 (Exhibit I-6).

nutraceutical HECs produced at its Brazilian, Indian, and Croatian facilities to the U.S. market.²³⁸ Petitioner does not have insight into ACG's possible supply to the U.S. market of nutraceutical HECs produced by its facilities in Thailand.

As noted above, Suheung is a South Korean HEC producer with manufacturing facilities in South Korea and Vietnam. It is Petitioner's understanding that Suheung supplies HECs produced in these facilities to both the nutraceutical and pharmaceutical segments of the U.S. market.²³⁹

The nutraceutical segment of the U.S. HECs market is characterized by intense competition between imports and domestic production. The market is fragmented, with a high number of foreign suppliers beyond ACG and Suheung. As noted in the 2023 Kline Report, in the nutraceutical segment, [

J. 240 Other foreign suppliers active in the nutraceutical segment of the U.S. HEC market include Qualicaps Brazil, BioCaps, Healthcaps, and Farmacapsulas / CapsCanada. 241

See Affidavit of Michael Goetter at P 7 (Exhibit I-6).

See Affidavit of Michael Goetter at 8 (Exhibit I-6).

See Kline, Empty Hard Capsules: United States at 67 (Exhibit I-3).

See Kline, Empty Hard Capsules: United States at 71 (Exhibit I-3); see also Affidavit of Michael Goetter at PP 6, 9-10 (Exhibit I-6).

c. Contract vs. Transaction-by-Transaction Sales

Petitioner conducts the majority of its HEC sales in the U.S. market on an effectively transaction-by-transaction basis.²⁴² Specifically, as Mr. Goetter explains in his affidavit:

In recent years, Lonza has conducted the majority of its annual U.S. HECs sales (by revenue) ([70] percent in 2024 to date) through non-binding transactions. While Lonza typically sets initial prices for transactional customers at the start of each year, such prices are subject to adjustment throughout the year because they are not contractually determined. Therefore, the majority of Lonza's sales are similar to sales on a transaction-by-transaction basis.²⁴³

To the best of Petitioner's knowledge and belief, Qualicaps USA and many of the subject producers (*e.g.*, ACG, Suheung, and Qualicaps Brazil) also conduct the majority of their U.S. HEC sales on an effectively transaction-by-transaction basis.²⁴⁴ This focus on non-contract-based sales contributes to the high price sensitivity in the U.S. HEC market.

H. The U.S. Industry Is Experiencing Material Injury by Reason of Dumped and Subsidized Imports from the Subject Countries

The U.S. HEC industry is experiencing material injury by reason of subject imports from Brazil, China, India, and Vietnam.

1. The Commission Should Cumulate Imports from All Subject Countries for its Material Injury Analysis — 19 U.S.C. § 1677(7)(G)

For purposes of evaluating the volume of subject imports and the effects of subject imports for a determination of material injury, the Act requires the Commission to cumulate subject imports from all countries as to which petitions were filed on the same day, if such

See Affidavit of Michael Goetter at P 19 (Exhibit I-6).

See Affidavit of Michael Goetter at P 19 (Exhibit I-6).

See Affidavit of Michael Goetter at P 19 (Exhibit I-6).

imports compete with each other and with the domestic like product in the U.S. market.²⁴⁵ In its assessments of whether to cumulate subject imports, the Commission has generally considered four factors: (1) fungibility ("including consideration of specific customer requirements and other quality related questions");²⁴⁶ (2) the presence of sales or offers to sell in the same geographic market; (3) common or similar channels of distribution; and (4) simultaneous presence in the market.²⁴⁷ No one factor is determinative, and the aforementioned list of factors is not exclusive.²⁴⁸ Rather, the Commission may consider any factors bearing on the conditions of competition when conducting a cumulation analysis. Moreover, the Commission need only find a "reasonable overlap" of competition between the domestic like product and subject imports to determine that it must cumulate subject imports.²⁴⁹

Here, this Petition was filed on the same day with respect to imports of HECs from Brazil, China, India, and Vietnam. As shown below, the subject imports of HECs compete with each other and with the domestic like product in the U.S. market. Therefore, all requirements for

²⁴⁵ 19 U.S.C. § 1677(7)(G)(i).

Accord Certain Carbon and Alloy Steel Cut-To-Length Plate from Austria, Belgium, Brazil, China, France, Germany, Italy, Japan, Korea, South Africa, Taiwan, and Turkey, Inv. Nos. 701-TA-559-561 and 731-TA-1317-1328 (Preliminary), USITC Pub. No. 4615 (May 2016) at 24.

See Cold-Rolled Steel Flat Products from Brazil, China, India, Japan, South Korea, and the United Kingdom, Inv. Nos. 701-TA-540-543 and 731-TA-1283- 1287 and 1290 (Review), USITC Pub. No. 5339 (May 2022) at IV-12; see also Tenaris Bay City, Inc. v. United States, 2024 WL 1693878, at *4 (Ct. Int'l Trade 2024).

See Goss Graphics Sys., Inc. v. United States, 216 F.3d 1357, 1362 (Fed. Cir. 2000); Noviant OY v. United

States, 451 F.Supp.2d 1367, 1379 (2006).

See, e.g., Mukand Ltd. v. United States, 20 CIT 903, 909, 937 F. Supp. 910, 916 (1996). The Statement of Administrative Action (SAA) to the Uruguay Round Agreements Act (URAA) expressly states that "the new section will not affect current Commission practice under which the statutory requirement is satisfied if there is a reasonable overlap of competition." H.R. Rep. No. 103-316, Vol. I at 848 (1994) (citing Fundicao Tupy, 678 F. Supp. at 902); see Goss Graphic Sys., Inc. v. United States, 33 F. Supp. 2d 1082, 1087 (Ct. Int'l Trade 1998) ("cumulation does not require two products to be highly fungible"); Wieland Werke, AG v. United States, 718 F. Supp. 50, 52 (Ct. Int'l Trade 1989) ("Completely overlapping markets are not required.").

cumulation are met for imports from the subject countries, and the Commission must cumulate the subject imports for purposes of its material injury analysis.

a. Fungibility

There is a high degree of fungibility between HECs imported from each of the subject countries and the domestic like product. Market analysts describe HECs as a commodity product for which [

]. HECs, and the HECs of various other market players from the subject countries, are also of a quality comparable to the top [] suppliers mentioned above. Moreover, as explained in the 2023 Kline Report, the U.S. HEC market [] in which [

J.²⁵² Industry players and end-users agree that HECs are a commodity product and that subject imports are highly interchangeable with each other and with U.S.-produced HECs.²⁵³ As Mr. Goetter explains in his affidavit: "the vast majority of the volumes produced by Lonza are interchangeable with subject imports, such as standard-sized gelatin or hydroxypropyl methylcellulose ("HPMC") capsules for use in the pharmaceutical and nutraceutical markets."²⁵⁴ Indeed, certain customers have explicitly told Petitioner that they consider HECs to be a commodity product.²⁵⁵ As Mr. Goetter attests in his affidavit, price is the

See Kline, Empty Hard Capsules: United States at 46 (Exhibit I-3).

See Affidavit of Michael Goetter at P 24 (Exhibit I-6).

See Kline, Empty Hard Capsules: United States at 32 (Exhibit I-3).

See Affidavit of Michael Goetter at PP 23-24 (Exhibit I-6).

See Affidavit of Michael Goetter at 24 (Exhibit I-6).

See Affidavit of Michael Goetter at P 23 (Exhibit I-6).

primary factor affecting pharmaceutical and nutraceutical manufacturers' HEC purchasing decisions in almost all instances.²⁵⁶

As explained by Kline, the [

].²⁵⁷ The fact that U.S. purchasers [

I demonstrates a high degree of

product fungibility across suppliers to the U.S. market.

The substantial number of Petitioner's lost sales described in **Exhibit I-69** further demonstrates that HECs from any subject country can easily be substituted for domestically-produced HECs. In his affidavit, Mr. Goetter states that many of Petitioner's lost sales involved customers that [

J.²⁵⁸ The fact that Petitioner has suffered numerous lost sales of this nature demonstrates that the subject producers manufacture HECs that are highly fungible with domestically-produced HECs.

Petitioner manufactures HECs with a range of characteristics. This includes: gelatin and vegetable polymer-based HECs; TiO₂-free opaque HECs; HECs of varying sizes and colors; HECs that can contain ingredients of different consistencies; and immediate and modified release HECs. Producers in each of the four subject countries are also able to produce HECs

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See Affidavit of Michael Goetter at P 23 (Exhibit I-6).

See Kline, Empty Hard Capsules: United States at 32 (Exhibit I-3).

See Affidavit of Michael Goetter at P 30 (Exhibit I-6).

with these features.²⁵⁹ Various subject producers can also produce HECs with other characteristics offered by Petitioner, *e.g.*, dry-powder inhalation ("DPI") HECs and enrobing caplets.²⁶⁰ Further, the HECs produced by the U.S. producers and the subject producers serve the exact same functions—*i.e.*, to deliver ingredients to patients/consumers in an efficient and regulated manner.

b. Same Geographic Markets

Based on information reasonably available to Petitioner, Petitioner believes that sales of HECs imported from the subject countries and sales of U.S.-produced HECs are present in all six major U.S. geographic regions (*i.e.*, the Northeast, Midwest, Southeast, Central Southwest, Mountains, and Pacific Coast regions). Petitioner sells and offers to sell its HECs to purchasers located in all of these regions.²⁶¹ Petitioner's Vice President and Regional Business Unit Head – Americas, Michael Goetter, attests that, in his experience, subject imports are also sold or offered for sale "broadly across the United States."²⁶²

U.S. Census import port-of-entry data downloaded from the Commission's DataWeb corroborates Petitioner's understanding that subject imports are sold across all U.S. regions.

See Lonza, Orange Book at 22 (Exhibit I-8); see also Healsee Capsules website, Titanium Dioxide Free Vegetable Capsule, https://www.capshealsee.com/tio2-free-hpmc/titanium-dioxide-free-vegetable-capsule.html
(Exhibit I-61); Healsee Capsules, Vegetable Capsules Product Brochure (Exhibit I-62); BioCaps website, Gelatin Capsules, https://biocaps.net/portfolio/gelatin-capsule/ (Exhibit I-63); BioCaps website, Vegetable Capsules Bio-V, https://biocaps.net/portfolio/vegetable-capsules-bio-v/ (Exhibit I-64); Qualicaps website, product profiles, https://qualicaps.com/Capsules/pharma (Exhibit I-65); ACG Product Profiles Brochure (Exhibit I-66); HealthCaps India website, Products: Empty Capsules, https://www.healthcapsindia.com/products-empty-capsules (Exhibit I-67); Suheung Capsule Embo Caps® Brochure (Exhibit I-56); ACG Capsules Range Brochure (2017) (Exhibit I-55).

See Lonza, Orange Book at 22 (Exhibit I-8).

See Affidavit of Michael Goetter at P 18 (Exhibit I-6).

See Affidavit of Michael Goetter at P 18 (Exhibit I-6).

Specifically, DataWeb data for imports for consumption under HTSUS subheadings 9602.00.1040 and 9602.00.5010 demonstrate that, between 2021 and Q2 2024:

- Imports of HECs from Brazil entered the United States from the Ports of Los Angeles, New York City, and Miami (suggesting that Brazilian HECs are at least sold in the Pacific Coast, Northeastern, and Southeastern regions of the United States);
- Imports of HECs from China entered the United States from 21 different ports across the Southeastern, Northeastern, Midwestern, Central Southwestern, Mountains, and Pacific Coast regions of the United States (suggesting that Chinese HECs are sold in all six regions);
- Imports of HECs from India entered the United States from 14 different ports across the Southeastern, Northeastern, Midwestern, Central Southwestern, Mountains, and Pacific Coast regions of the United States, and Puerto Rico (suggesting that Indian HECs are sold in all of these regions); and
- Imports of HECs from Vietnam entered the United States from 7 different ports across the Southeastern, Northeastern, Midwestern, Mountains, and Pacific Coast regions of the United States (suggesting that Vietnamese HECs are sold in all of these regions).²⁶³

For these reasons, Petitioner believes that sales of, or offers to sell, HECs from the subject countries and HECs produced by the U.S. industry are present in all of the same U.S. geographic markets.

c. Common and Similar Channels of Distribution

Petitioner primarily sells HECs directly to end-users in the U.S. market.²⁶⁴ Petitioner is aware of subject producers that sell HECs in the U.S. market directly to end-users and through

See Port-of-Entry Import Data for the Subject Merchandise (Exhibit I-76).

See Affidavit of Michael Goetter at P 15 (Exhibit I-6).

intermediate distributors.²⁶⁵ However, to the best of Petitioner's knowledge, prominent subject producers active in the U.S. market (namely ACG, Suheung, and Qualicaps Brazil) "also focus on direct sales to end-users in the U.S. market."²⁶⁶

d. Simultaneous Presence in the U.S. Market

U.S.-produced HECs and the subject merchandise were simultaneously present in the U.S. market during the POI. Based on U.S. Census data for imports for consumption under HTSUS subheadings 9602.00.1040 and 9602.00.5010, subject imports from China, India, and Vietnam entered the United States in every month between January 2021 and June 2024. Subject imports from Brazil entered the United States in roughly three quarters of the months between January 2021 and June 2024. Further, Mr. Goetter attests that, in his experience, sales of, and offers to sell, subject imports in the United States also occur throughout the year. 268

e. Conclusion

As shown above, all requirements for cumulation are met for subject imports from Brazil, China, India, and Vietnam. Therefore, the Commission must cumulate the subject imports for purposes of its material injury analysis.

2. The Volume of Subject Imports Is Significant with Adverse Effects to the Domestic Industry — 19 U.S.C. § 1677(7)(C)(i)

The Act provides that the "Commission shall consider whether the volume of imports of the merchandise, or any increase in that volume, either in absolute terms or relative to production

See Affidavit of Michael Goetter at PP 15-16 (Exhibit I-6).

See Affidavit of Michael Goetter at 15 (Exhibit I-6).

See Monthly Import Data for the Subject Merchandise (January 2021 – June 2024) (Exhibit I-77).

See Affidavit of Michael Goetter at P 18 (Exhibit I-6).

or consumption in the United States, is significant."²⁶⁹ As explained above, data under HTSUS subheadings 9602.00.1040 and 9602.00.5010 provide the best information available to Petitioner regarding subject imports of HECs. These data show that the volume of subject imports, both in absolute terms and relative to U.S. consumption and production, is significant within the meaning of the relevant statutory provision.

First, imports of the subject merchandise are significant in absolute terms. Annual subject import volumes have been above 39 billion units in every full year of the POI (and as high as 44.42 billion units in 2022).²⁷⁰ Further, subject imports increased by a staggering 41.55 percent between H1 2023 and H1 2024 (*i.e.*, from 15.81 billion units to 22.38 billion units).²⁷¹ The conclusions to be drawn from these data are undeniable—subject import volumes have flooded the U.S. market.

Second, since 2021, subject imports have gained significant U.S. market share. Between 2021 and 2023, subject imports went from holding [30.00] percent to [40.00] percent of total U.S. consumption of HECs.²⁷² Meanwhile, U.S. producers and non-subject imports lost U.S. market share during this period. Further, between H1 2023 and H1 2024, subject imports gained [*] percentage points in U.S. market share while U.S. producers lost [*] percentage points during this half-on-half period.²⁷³ Indeed, in H1 2024, subject import volumes were nearly [*] times the volume of Petitioner's half-year shipments.²⁷⁴ Throughout the POI,

²⁶⁹ 19 U.S.C. § 1677(7)(C)(i).

See Volume and Value of Subject Imports (Exhibit I-48).

See Volume and Value of Subject Imports (Exhibit I-48)

See Market Share Calculations (Exhibit I-50).

See Market Share Calculations (Exhibit I-50).

See Market Share Calculations (Exhibit I-50).

subject imports' increase in market share has come at the direct expense of the domestic industry.

Subject imports also rose relative to U.S. producers' production volumes over the POI. Petitioner's annual U.S. production dropped from [50,000,000,000] units in 2021 to [40,000,000,000] units in 2023.²⁷⁵ Information concerning Qualicaps USA's actual U.S. production volumes in 2021 and 2023 are unavailable to Petitioner. However, assuming that Qualicaps USA had stable capacity of [11,000,000,000] units and operated at its 2022 capacity utilization rate of [90] percent across the entire POI,²⁷⁶ total U.S. production in 2021 would have been [59,000,000,000] units, and total U.S. production in 2023 would have been [53,000,000,000] units. As a result, subject imports would have accounted for [70.00] percent of U.S. producers' production volumes in 2021, but [80.00] percent of U.S. producers' production volumes in 2023.

Further, as a share of total imports (subject and non-subject) to the U.S. market, subject imports rose from [45.00] percent of all imports in 2021 to [55.00] percent of all imports in 2023. The increase in subject imports' share of total HEC imports between H1 2023 and H1 2024—from [50.00] percent to [55.00] percent—is also notable.²⁷⁷

For the reasons discussed above, the volume—and the increase in volume—of subject imports is significant.

²⁷⁵ See Petitioner's U.S. Operational and Financial Performance (Exhibit I-87).

²⁷⁶ See Lonza, Orange Book at 9 (Exhibit I-8).

See Market Share Calculations (Exhibit I-50).

3. Subject Imports Have Had Adverse Price Effects for the Domestic Industry — 19 U.S.C. § 1677(7)(C)(ii)

In evaluating the effect of subject imports on prices, the Commission must consider whether there has been significant underselling by the subject imports, and whether imports significantly suppressed or depressed domestic prices.²⁷⁸ Evidence reasonably available to Petitioner indicates that subject imports have undersold the domestic like product throughout the POI. These dumped and subsidized prices of subject imports both depressed U.S. prices and suppressed prices by preventing the U.S. producers from adequately raising their prices in response to increasing costs. For these reasons, the Commission should determine that subject imports had significant negative price effects on the domestic like product.

Subject imports pervasively and extensively undersold the domestic like product throughout the POI. As demonstrated in **Exhibit I-51**, the average unit values ("AUVs") of subject imports were below the AUVs of Petitioner's U.S. shipments in every quarter of the POI.²⁷⁹ As illustrated in **Exhibit I-51**, the margin by which the AUVs of subject imports were below those of Petitioner over the POI ranged from [12.00] percent to [45.00] percent, with an overall average of [30.00] percent.²⁸⁰

The substantial dumping margins calculated in Volumes II through V of this Petition serve as further evidence of underselling by the subject imports.

Subject imports have put such intense pricing pressure on Petitioner that Petitioner has had to lower certain of its U.S. HEC prices despite rising costs of production, and has been

²⁷⁸ 19 U.S.C. § 1677(7)(C)(ii).

See Underselling Analysis (Exhibit I-51).

See Underselling Analysis (Exhibit I-51).

unable to adequately raise certain of its U.S. HEC prices in response to these increasing costs.

As a result, Petitioner has suffered a "cost-price squeeze." Specifically, between 2021 and 2023,

Petitioner's ratio of the cost of goods sold ("COGS") to net sales has increased from [25.00]

percent to [35.00] percent.²⁸¹

Petitioner's numerous instances of lost sales and lost revenues further demonstrate subject imports' adverse price effects on Petitioner. As illustrated in **Exhibit I-69**, intense competition from unfairly traded subject imports has repeatedly forced Petitioner to lower its prices in order to retain sales.²⁸²

4. Subject Imports Have Adversely Impacted the Domestic Industry — 19 U.S.C. § 1677(7)(C)(iii)

The Act provides that in examining the impact of subject imports, "the Commission shall evaluate all relevant economic factors which have a bearing on the state of the industry in the United States." These factors include output, sales, market share, capacity utilization, inventories, employment, wages, productivity, gross profits, operating profits, net profits, cash flow, return on investment, return on capital, ability to raise capital, ability to service debts, research and development, and factors affecting domestic prices. No single factor is dispositive, and all relevant factors are considered "within the context of the business cycle and conditions of competition that are distinctive to the affected industry." 285

See Petitioner's U.S. Operational and Financial Performance (**Exhibit I-87**); see also Market Share Calculations (**Exhibit I-50**).

See Lost Sales and Lost Revenues (Exhibit I-69).

²⁸³ 19 U.S.C. § 1677(7)(C)(iii).

²⁸⁴ See 19 U.S.C. § 1677(7)(C)(iii).

²⁸⁵ See 19 U.S.C. § 1677(7)(C)(iii).

As noted in Section II.C above, Petitioner accounts for the vast majority of U.S. production of HECs (over 80 percent of total estimated U.S. production in 2023). Therefore, the injuries that subject imports have caused Petitioner generally reflect the impact of subject imports on the U.S. domestic industry. As explained below, Petitioner has suffered extensive harms on almost every dimension as a result of dumped and subsidized subject imports.

First, Petitioner has experienced extensive damage to its U.S. production and sales.

Between 2021 and 2023, Petitioner's U.S. production volumes fell from [50,000,000,000] units to [45,000,000,000] units, and its U.S. shipments fell from [25,000,000,000] units to [19,000,000,000] units. Comparisons between H1 2023 and H1 2024 indicate that Petitioner's U.S. production and sales volumes continue to suffer, with production volumes dropping from [21,000,000,000] units to [12,000,000,000] units and U.S. shipments dropping from [9,900,000,000] units to [5,500,000,000] units over this half-on-half period. These declines in U.S. production and sales volumes are [

[] million to [] million between 2021 and 2023, and [] from [] million to [] million between H1 2023 and H1 2024.²⁸⁹

Second, Petitioner lost [*] percentage points of U.S. market share between 2021 and 2023, while subject imports gained [*] percentage points of U.S. market share over that

See Petitioner's U.S. Operational and Financial Performance (**Exhibit I-87**); see also Market Share Calculations (**Exhibit I-50**).

See Petitioner's U.S. Operational and Financial Performance (**Exhibit I-87**); see also Market Share Calculations (**Exhibit I-50**).

See Affidavit of Michael Goetter at P 27 (Exhibit I-6).

See Petitioner's U.S. Operational and Financial Performance (Exhibit I-87).

same period.²⁹⁰ Data for H1 2024 demonstrate that subject imports have continued to capture significant market share directly from Petitioner in the first half of this year. Indeed, between H1 2023 and H1 2024, Petitioner lost an astonishing [*] percentage points of U.S. market share, while subject imports gained almost that exact same amount—[*] percentage points of U.S. market share.²⁹¹ The data could not make it any clearer that subject imports' market share gains are at the direct expense of the U.S. HEC industry.

Third, Petitioner's capacity utilization declined severely between 2021 and 2023, from [85.00] percent to [70.00] percent. Comparisons between H1 2023 and H1 2024 indicate that Petitioner's capacity utilization has [] (specifically, from [75.00] percent in H1 2023 to an abysmal [45.00] percent in H1 2024).²⁹² Petitioner also [

reduced demand for Petitioner's HECs as a result of competition from dumped and subsidized subject imports.

1.²⁹³ All of this has been due to

Fourth, Petitioner's inventories of HECs have risen as subject imports continue to capture sales at Petitioner's expense. Specifically, Petitioner's year-end inventories rose by nearly [] capsules between 2021 and 2023.²⁹⁴

<u>Fifth</u>, unfair competition from dumped and subsidized subject imports has broadly damaged Petitioner's financial performance metrics (e.g., COGS-to-net sales ratio, income, cash

See Market Share Calculations (Exhibit I-50).

See Market Share Calculations (Exhibit I-50).

See Petitioner's U.S. Operational and Financial Performance (Exhibit I-87).

See Affidavit of Michael Goetter at P 32 (Exhibit I-6).

See Petitioner's U.S. Operational and Financial Performance (Exhibit I-87).

flows, and profitability). The below table shows the downward trends across Petitioner's operational and financial performance:

Summary of Petitioner's Operational and Financial Performance Quantity (in 1,000 units) and value (in USD)					
	2021	2022	2023	H1 2023	H1 2024
Practical Capacity	[]
Production]	40,000,000]
Capacity Utilization	I			75.00%]
Net Sales Values	[210,000,000				J
Total Sales Quantities	[15,000,000]
End-of- Period Inventories	[8,000,000]
Cost of Goods Sold ("COGS")	[50,000,000				22,000,000]
COGS/Net Sales	[]
Gross Income	I				J
Operating Income	I	65,000,000]
Gross Profit Margin	[70.00%]
Operating Profit Margin	[40.00%		J

Petitioner has been so thoroughly harmed by the flood of unfairly traded subject imports that it has been forced to lay off a significant portion of its workforce, including many of its

highly-skilled HEC manufacturing workers.²⁹⁵ To date, since the third quarter of 2023, Petitioner has been "forced to shed [100] HEC production-related workers" (*i.e.*, [15] percent of Petitioner's workforce as of the third quarter of 2023).²⁹⁶ As Mr. Goetter states in his affidavit, "Lonza has also been unable to increase wages for its workers commensurately with inflation."

<u>Finally</u>, as a result of the sales and revenues it has lost to subject imports, Petitioner has been [

1.²⁹⁸ Indeed, as a result of the

financial damage caused by subject imports, Petitioner [

 $1.^{299}$

As Mr. Goetter attests in his affidavit: [

 $1.^{300}$

Petitioner has not conducted HEC-related R&D in Greenwood since 2017. Despite an interest in resuming such R&D activities over the POI, Petitioner has been unable to commence any HEC-related R&D in Greenwood due to a lack of adequate cash flow.³⁰¹ Moreover,

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See Affidavit of Michael Goetter at P 33 (Exhibit I-6).

See Affidavit of Michael Goetter at P 33 (Exhibit I-6).

See Affidavit of Michael Goetter at P 33 (Exhibit I-6).

See Affidavit of Michael Goetter at P 34 (Exhibit I-6).

See Affidavit of Michael Goetter at 36 (Exhibit I-6).

See Affidavit of Michael Goetter at P 36 (Exhibit I-6).

See Affidavit of Michael Goetter at P 35 (Exhibit I-6).

Petitioner has [

].302

5. Conclusion

For the foregoing reasons, the Commission should find that the U.S. HEC industry is materially injured by reason of subject imports from Brazil, China, India, and Vietnam.

I. The Domestic Industry Is Threatened with Further Material Injury by Reason of Subject Imports from Brazil, China, India, and Vietnam

As part of its analysis of whether the domestic industry is threatened with material injury by reason of the subject imports, the Act requires the Commission to consider a number of factors, including: (1) the countervailable subsidies involved; (2) any existing unused production capacity or imminent, substantial increase in production capacity in the exporting country; (3) a significant rate of increase in the volume or market penetration of the subject imports; (4) whether the subject imports are entering at prices that are likely to have a significant depressing or suppressing effect on domestic prices; (5) inventories of the subject merchandise; (6) the potential for product-shifting in the foreign country; (7) actual and potential negative effects on existing development and production efforts of the domestic industry; and (8) any other demonstrable adverse trends that indicate the probability of material injury by reason of the subject imports.³⁰³ The Act further specifies that the Commission shall consider these factors "as a whole" in determining whether further dumped or subsidized imports are imminent and

³⁰³ 19 U.S.C. § 1677(7)(F)(i).

See Affidavit of Michael Goetter at \$\mathbb{P}\$ 35 (Exhibit I-6).

whether material injury by reason of such imports would occur unless relief is granted to the domestic industry.³⁰⁴

As the discussion below demonstrates, the evidence reasonably available to Petitioner indicates that, in addition to suffering current material injury, the domestic HEC industry is also threatened with further material injury by reason of the unfairly traded subject imports from Brazil, China, India, and Vietnam.

1. The Commission Should Cumulate Imports from All Subject Countries for Any Threat Analysis — 19 U.S.C. § 1677(7)(H)

Under the Act, in determining threat of material injury, the Commission may cumulatively assess the volume and price effects of imports of the subject merchandise from all countries as to which petitions were filed on the same day, if such imports compete with each other and with the domestic like product in the U.S. market.³⁰⁵ The Commission should cumulate subject imports from Brazil, China, India, and Vietnam for purposes of its threat analysis, because: (1) petitions were filed on the same day with respect to imports of HECs from all four countries; and (2) as explained in Section III.H.1 above, the subject imports compete with each other and the domestic like product in the U.S. market. There is no indication that conditions of competition between subject imports and the domestic like product will change in any material respect in the imminent future. Moreover, during the POI, producers from all four subject countries sold substantial volumes of HECs in the U.S. market at prices that allowed them to capture sales and market share from the domestic industry. In such circumstances, the

³⁰⁴ 19 U.S.C. § 1677(7)(F)(ii).

³⁰⁵ 19 U.S.C. § 1677(7)(H).

Commission should exercise its discretion to cumulate subject imports from Brazil, China, India, and Vietnam.

- 2. Relevant Economic Factors Indicate the Domestic Industry Is Threatened with Further Material Injury 19 U.S.C. § 1677(7)(F)
 - a. Countervailable Subsidies Encourage Production and Export of HECs from Brazil, China, India, and Vietnam

As part of its threat analysis, the Commission considers whether "a countervailable subsidy is involved" and, in particular, "whether the countervailable subsidy is a subsidy described in Article 3 or 6.1" of the WTO Agreement on Subsidies and Countervailing Measures ("SCM Agreement").³⁰⁶ Article 3 of the SCM Agreement describes subsidies that are prohibited because they are contingent upon export performance or upon the use of domestic over imported goods.³⁰⁷

As set out in Volumes VI, VII, VIII, and IX of this Petition, the Governments of Brazil, China, India, and Vietnam provide numerous countervailable subsidies—including various subsidies that are contingent upon export performance and subsidies that encourage the expansion of domestic manufacturing capacity—to HEC producers. These subsidies threaten the U.S. HEC industry.

1:

For example, in India, Kline reports that [

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³⁰⁶ 19 U.S.C. § 1677(7)(F)(i)(I).

Agreement on Subsidies and Countervailing Measures, Marrakesh Agreement Establishing the World Trade Organization, April 14, 1994, Annex 1, 1867 U.N.T.S. 14, at Art. 3.

].308

In addition to the PLI and other subsidies provided by the Government of India, Indian HEC producers also benefit from state-level subsidy programs.

In China, the Chinese government maintains extensive industrial policies that direct and manage the country's economic and industrial growth and development. These industrial policies have resulted in subsidy programs that confer massive benefits on the Chinese pharmaceuticals and related industries, including producers of Chinese HECs and their inputs.

In Vietnam, the Vietnamese government maintains several subsidy programs that benefit HEC exporters, as well as HEC producers located in certain designated geographic areas. In addition to subsidies provided by the Government of Vietnam, HEC producer, Suheung Vietnam Co., Ltd, also benefits from transnational subsidies from the Government of Korea.

Finally, in Brazil, the Brazilian government subsidizes HEC producers, which also benefit from subsidies offered at the state and municipal level.

b. Producers in Subject Countries Have Ample and Expanding Capacity, and Incentive to Export Massive Amounts of HECs to the United States

In determining whether the domestic industry is threatened with material injury, the Commission also considers "any existing unused production capacity or imminent, substantial increase in production capacity in the {subject countries} indicating the likelihood of substantially increased imports of the subject merchandise into the United States, taking into

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See Kline, Empty Hard Capsules: India at 63, 88 (Exhibit I-58).

account the availability of other export markets to absorb any additional exports."³⁰⁹ As detailed below, the subject producers have massive levels of unused production capacity, and are continuing to expand their capacity by substantial amounts. Further, the subject producers have strong incentives to continue exporting substantial volumes of HECs to the United States.

<u>First</u>, HEC producers in the subject countries have significant unused HECs manufacturing capacity. For example, assessments conducted by Petitioner based on available market intelligence indicate that, in 2022, ACG Brazil operated at just [60] percent capacity.³¹⁰ Kline also reports that [

1.311 In China, Kline reports [

1.312 In India, Kline

reports that [

 $1.^{313}$

Second, since 2021, producers of HECs in the subject countries have, and are continuing to undertake, significant capacity expansion initiatives. For example, Chinese HEC manufacturer Qingdao Yiqing Biotechnology Co., Ltd ("Yiqing Biotech") is planning to build a

³⁰⁹ 19 U.S.C. § 1677(7)(F)(i)(II).

See Lonza, Orange Book at 10 (Exhibit I-8).

See Kline, Empty Hard Capsules: Brazil at 67 (Exhibit I-57).

See Kline, Empty Hard Capsules: China at 65 (Exhibit I-59).

See Kline, Empty Hard Capsules: India at 39, 41, 61, 63, 68, 75, 77, 79, 89, 92 (Exhibit I-58).

new HEC manufacturing facility in Shandong by 2026 to increase its capacity in China.³¹⁴ With this expansion, Yiqing is expected to "more than double {its manufacturing} capacity" relative to 2020.³¹⁵ Another Chinese manufacturer, Anhui Huangshan Capsule Co., Ltd. ("Huangshan Capsule"), added four new HEC production lines to its Hongchuan plant in 2021. Relative to its 2020 manufacturing capacity, Huangshan Capsule is expected to increase its HEC manufacturing capacity by more than 50 percent by 2026.³¹⁶ Furthermore, Kline reports that [

 $1.^{317}$

Indian HEC manufacturers have also been undertaking or planning significant capacity expansions. The most notable of these expansions involves ACG, the largest HEC manufacturer in India. In December 2021, ACG announced that it had signed a Memorandum of Understanding with the State of Maharashtra to build the largest HEC manufacturing facility on the Asian continent in the state, with a proposed investment of approximately \$100 million (over INR 600 crores). Construction of this facility—which will focus on HPMC HECs—is underway, with completion expected in 2025. ACG plans for this new facility to have a

See Lonza, HEC Competitive Landscape Deep Dive Review: Tier 2 Indian & Chinese Suppliers (June 2022) ("Lonza, Indian & Chinese Suppliers") at 26 (Exhibit I-78).

See Lonza, *Indian & Chinese Suppliers* at 26 (Exhibit I-78).

See Lonza, *Indian & Chinese Suppliers* at 27 (Exhibit I-78).

See Kline, Empty Hard Capsules: China at 69, 77 (Exhibit I-59).

See Sebastian Krawiec, ACG to build Asia's largest capsule manufacturing plant in the Indian state of Maharashtra, Nutritional Outlook (Dec. 1, 2021), https://www.nutritionaloutlook.com/view/acg-to-build-asia-s-largest-capsule-manufacturing-plant-in-the-indian-state-of-maharashtra (Exhibit 1-79).

See 800 Crore Milestone: ACG Vegetarian Capsule Production In Maharashtra, Projx News (Mar. 30, 2024), https://projxnews.com/blog/800-crore-milestone-acg-vegetarian-capsule-production-in-maharashtra (Exhibit I-80).

production capacity of 40 billion capsules per year.³²⁰ In addition, ACG has undertaken an approximately INR 575 crore HPMC raw material manufacturing project in Dahej, Gujarat, also expected to be completed in Q1 2025.³²¹ As a result of these projects, ACG's product mix is expected to become skewed toward HPMC capsules.³²²

In addition, since 2020, HealthCaps India Ltd. ("HealthCaps") has been working to double its HEC manufacturing capacity by 2026 (to 40 billion capsules per year), with a focus on plant-based capsule products.³²³

Further, the 2022-2023 Annual Report for Natural Capsules Ltd. ("Natural Capsules") boasts on its first page that, between 2020 and 2023, the company has "embarked on an ambitious expansion plan, exponentially increasing our capacity in the capsules business."³²⁴ Specifically, between 2020 and 2023, the company expanded its HEC manufacturing capacity in India by 80.5 percent—from 10.8 billion units per year to 19.5 billion units per year.³²⁵ However, Natural Capsules does not plan to stop there; in its annual report, it highlights plans to

See Sebastian Krawiec, ACG to build Asia's largest capsule manufacturing plant in the Indian state of Maharashtra, Nutritional Outlook (Dec. 1, 2021), https://www.nutritionaloutlook.com/view/acg-to-build-asia-s-largest-capsule-manufacturing-plant-in-the-indian-state-of-maharashtra (Exhibit I-79).

See CareEdge Ratings, ACG Associated Capsules Private Limited (Dec. 7, 2023) at 2 (Exhibit I-74).

See Lonza, Indian & Chinese Suppliers at 32 (Exhibit I-78).

See Natural Capsules Annual Report (2022-2023) at 1 (Exhibit I-83).

See Natural Capsules Annual Report (2022-2023) at 4, 56 (Exhibit I-83).

increase capacity to 22 billion capsules per year.³²⁶ While Natural Capsules may not yet export to the United States, it is well positioned and poised to enter new export markets. Indeed, the 2022-2023 Annual Report for Natural Capsules recognizes that "{w}ith exports spanning more than 30 countries, international trade has become a pivotal revenue driver" for the company, and the company "aims to make a lasting impact and establish a prominent global presence." The company has a stated goal of "target{ing} untapped geographies and expand{ing} the company's global footprint." ³²⁸

Kline also reports that several Indian HEC producers have expanded capacity since 2021, including: [

].329

In Vietnam, Kline reports that [

 $1.^{330}$

].331 [

See Natural Capsules Annual Report (2022-2023) at 4, 7 (Exhibit I-83).

See Natural Capsules Annual Report (2022-2023) at 6 (Exhibit I-83).

See Natural Capsules Annual Report (2022-2023) at 27 (Exhibit I-83).

See Kline, Empty Hard Capsules: India at 77, 79 (Exhibit I-58).

See Kline, Empty Hard Capsules: Vietnam at 37, 38, 39, 42, 45, 50, 51, 57, 63, 66, 68 (Exhibit I-60).

See Kline, Empty Hard Capsules: Vietnam at 37, 45, 66 (Exhibit I-60).

 $1.^{332}$

], evidencing the Vietnamese HEC industry's focus on export markets including the United States.³³³

Third, the subject producers have strong incentives to target the U.S. HEC market. As noted in Section III.G.2, the U.S. HEC market is expected to grow by 2 to 3 percent each year in the coming years.³³⁴ The subject producers are poised to take advantage of this expanding U.S. market for HECs. Indeed, export markets—including the United States—are particularly attractive, if not vital, for the subject producers; according to Kline, [

 $1.^{335}$

Based on available market research and data, Petitioner has assessed that the global market for HECs will become increasingly saturated over the next five years, with global capacity expansions outpacing growth in global demand.³³⁶ In other words, available market intelligence indicates that global markets would be unable to absorb additional exports of HECs by the subject producers.

See Kline, Empty Hard Capsules: Vietnam at 37, 51, 57, 66 (Exhibit I-60).

See Kline, Empty Hard Capsules: Vietnam at 57, 58 (Exhibit I-60).

See Lonza Annual Report (2023) at 54 (Exhibit I-70).

See Kline, Empty Hard Capsules: Vietnam at 57 (Exhibit I-60); see also Kline, Empty Hard Capsules: India at 39, 92 (Exhibit I-58) (

^{]);} Kline, *Empty Hard Capsules: Brazil* at 67 (Exhibit I-57); Kline, *Empty Hard Capsules: China* at 65 (Exhibit I-59).

See Lonza, Orange Book at 17 (Exhibit I-8).

For the reasons explained above, the subject producers have ample ability and incentive to continue flooding the U.S. market with dumped and subsidized HECs.

c. The Volume and Market Share of Subject Imports Have Increased Significantly

The Commission also considers "a significant rate of increase of the volume or market penetration of imports of the subject merchandise indicating the likelihood of substantially increased imports" as part of its threat analysis.³³⁷

As explained in Section III.H.2 above, subject imports increased by an astounding 41.5 percent in H1 2024 relative to H1 2023. Further, while U.S. producers' market share declined over the POI, subject imports significantly expanded their market share—from [30.00] percent in 2021 to [40.00] percent in 2023, and then to an astounding [40.00] percent in H1 2024.³³⁸

d. Subject Imports Will Continue to Depress and Suppress U.S. Producers' Prices

As part of its threat analysis, the Commission considers "whether imports of the subject merchandise are entering at prices that are likely to have a significant depressing or suppressing effect on domestic prices, and are likely to increase demand for further imports.³³⁹ Subject imports had such effects during the POI and, in the absence of relief, will continue to have such effects in the near future.

As explained in Section III.H.3 above, comparative AUV data for subject imports and Petitioner's shipments, Petitioner's lost sales and lost revenue allegations, and the substantial

³³⁷ 19 U.S.C. § 1677(7)(F)(i)(III).

See Market Share Calculations (Exhibit I-50).

³³⁹ 19 U.S.C. § 1677(7)(F)(i)(IV).

dumping margins calculated in Volumes II through V demonstrate that subject imports pervasively and extensively undersold the domestic like product throughout the POI. Moreover, as described in Section III.H.3, competition from underpriced subject imports has prevented Petitioner from increasing its U.S. prices commensurately with its costs.

As illustrated in Exhibit I-51, AUV trends for H1 2024 indicate that subject imports continue to enter the United States at prices that are likely to have these depressive and suppressive effects. Specifically, in the first and second quarters of 2024, subject imports' AUVs were respectively [35.00] and [30.00] percent below those of Petitioner.³⁴⁰

HEC producers from the subject countries have every incentive to continue dumping low-priced and subsidized product into the U.S. market in order to undersell the U.S. producers and gain or maintain market share at U.S. producers' expense. As forecasted in the 2023 Kline Report discussing the market in 2022:

92

See Underselling Analysis (Exhibit I-51).

], {which

include Petitioner and Qualicaps}.341

Kline also reported in 2023 that, in India, [

1.342 Furthermore, in Vietnam, [

1.343

e. There Are Significant Inventories of Subject Merchandise in the Subject Countries

To assess whether the domestic industry is threatened with material injury by subject imports, the Commission will also consider inventories of the subject merchandise.³⁴⁴ Based on information reasonably available to Petitioner—including the overcapacity situation in each subject country—Petitioner believes that there are excessive inventories of the subject merchandise in the subject countries. Indeed, with respect to India, Kline highlights that

1.345

f. The Domestic Industry Is Vulnerable to Further Material Injury from Subject Imports

As a result of increasing imports of HECs from Brazil, China, India, and Vietnam at unfair prices, the U.S. industry's operational and financial health has been seriously damaged, making the industry vulnerable to further material injury. As explained in Section III.H.4, the U.S. producers lost significant U.S. market share over the POI (especially between H1 2023 and

See Kline, Empty Hard Capsules: United States at 68 (Exhibit I-3).

Kline, Empty Hard Capsules: India at 89, 92 (Exhibit I-58).

Kline, Empty Hard Capsules: Vietnam at 66 (Exhibit I-60).

³⁴⁴ 19 U.S.C. § 1677(7)(F)(i)(V).

See Kline, Empty Hard Capsules: India at 39, 41, 61, 67, 68, 75, 77, 89, 92, 98 (Exhibit I-58).

H1 2024) as a direct result of competition from underpriced subject imports.³⁴⁶ Petitioner, for its part, suffered declines in its production volumes, capacity utilization, U.S. sales volumes and values, and market share over the POI, as well as increases in its inventories. The deterioration in Petitioner's operational metrics led to a decline in its financial performance that would not have been so poor but for the significant and increasing presence of unfairly traded imports. As a result of its financial injuries, Petitioner has been unable to invest in its HECs operations and has been forced to shed [15] percent of its Greenwood workforce (as of Q3 2023).³⁴⁷

As Mr. Goetter states in his affidavit: "without relief from dumped and subsidized subject imports, there is [

1."348 Trade relief is

urgently needed to stem the injuries that Petitioner has suffered by reason of subject imports, and to prevent Petitioner from suffering any further.

For the reasons stated above, the domestic industry is threatened with further material injury by reason of cumulated subject imports from Brazil, China, India, and Vietnam.

IV. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that:

 The Department initiate AD and CVD investigations with respect to imports of HECs from Brazil, China, India, and Vietnam;

See Market Share Calculations (Exhibit I-50).

See Affidavit of Michael Goetter at P 33 (Exhibit I-6).

See Affidavit of Michael Goetter at P 37 (Exhibit I-6).

- 2. The Department determine that these imports from Brazil, China, India, and Vietnam are being sold at LTFV and are subsidized;
- 3. The Commission institute an import injury investigation with respect to imports of HECs from Brazil, China, India, and Vietnam; and
- 4. The Commission determine that these LTFV and subsidized imports are causing material injury and threatening further material injury to the domestic HEC producing industry.

Respectfully submitted,

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