

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

¹⁹⁵ See Affidavit of Michael Goetter at ¶ 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.¹⁹⁶ Moreover, among non-gelatin capsules, HPMC capsules are most prevalent in the U.S. market.¹⁹⁷

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.¹⁹⁸ 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).¹⁹⁹ 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

¹⁹⁶ See Kline, *Empty Hard Capsules: United States* at 40-44, 47-48 (Exhibit I-3).

¹⁹⁷ See Kline, *Empty Hard Capsules: United States* at 56-62 (Exhibit I-3).

¹⁹⁸ See Affidavit of Michael Goetter at ¶ 14 (Exhibit I-6).

¹⁹⁹ See Kline, *Empty Hard Capsules: United States* at 47-48 (Exhibit I-3).

²⁰⁰ 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.*, f.o.b., U.S. point of shipment, 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.

²⁰¹ See Affidavit of Michael Goetter at ¶ 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

Petitioner’s lost sales and revenues include instances involving some of its largest and most important customers, such as []. As Mr. Goetter explains in his affidavit, “between 2022 and 2024 to date, Lonza has lost [60] percent of its 2022 sales volumes to [].”²⁰⁵ In 2024, Petitioner lost a sale for [

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

²⁰² 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.

²⁰³ See Lost Sales and Lost Revenues (**Exhibit I-69**); see also Affidavit of Michael Goetter at ¶ 28 (**Exhibit I-6**).

²⁰⁴ See Affidavit of Michael Goetter at ¶ 29 (**Exhibit I-6**).

²⁰⁵ See Affidavit of Michael Goetter at ¶ 28 (**Exhibit I-6**).

²⁰⁶ 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 [

].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

²⁰⁷ See Affidavit of Michael Goetter at ¶ 30 (Exhibit I-6).

²⁰⁸ See Affidavit of Michael Goetter at ¶ 30 (Exhibit I-6).

²⁰⁹ See Affidavit of Michael Goetter at ¶ 30 (Exhibit I-6).

²¹⁰ See Affidavit of Michael Goetter at ¶ 31 (Exhibit I-6).

²¹¹ See Affidavit of Michael Goetter at ¶ 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 []²¹⁴ The 2023 Kline Report also recognizes that, in light of the high level of product fungibility, []²¹⁵], 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 []

²¹² See Affidavit of Michael Goetter at ¶ 23 (Exhibit I-6).

²¹³ See Affidavit of Michael Goetter at ¶ 23 (Exhibit I-6).

²¹⁴ See Kline, *Empty Hard Capsules: United States* at 48 (Exhibit I-3).

²¹⁵ Kline, *Empty Hard Capsules: United States* at 48 (Exhibit I-3).

].²¹⁶

Further, as mentioned in Section III.F above, 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.

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

²¹⁶ See Kline, *Empty Hard Capsules: United States* at 72 (Exhibit I-3).

²¹⁷ See Kline, *Empty Hard Capsules: United States* at 5, 94 (Exhibit I-3).

²¹⁸ See Kline, *Empty Hard Capsules: United States* at 56 (Exhibit I-3).

²¹⁹ 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.²²² 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

²²⁰ See Kline, *Empty Hard Capsules: United States* at 56, 61-62 (**Exhibit I-3**).

²²¹ See Lonza Annual Report (2023) at 54 (**Exhibit I-70**).

²²² See Kline, *Empty Hard Capsules: United States* at 82 (**Exhibit I-3**).

²²³ 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.

²²⁴ 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.”).

²²⁵ See Kline, *Empty Hard Capsules: United States* at 88 (**Exhibit I-3**).

²²⁶ See Kline, *Empty Hard Capsules: United States* at 89 (**Exhibit I-3**).

²²⁷ 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.”).

²²⁸ 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 low-priced 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

²²⁹ See Kline, *Empty Hard Capsules: United States* at 67 (**Exhibit I-3**).

²³⁰ See Affidavit of Michael Goetter at ¶ 5 (**Exhibit I-6**).

²³¹ See Qualicaps Corporate Brochure (2023) at 7 (**Exhibit I-52**).

²³² See Affidavit of Michael Goetter at ¶ 6 (**Exhibit I-6**).

²³³ 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 []²³⁵

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

²³⁴ 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_details.php?spkr_id=SPKR-20130305100822443648 (**Exhibit I-75**); Affidavit of Michael Goetter at ¶ 7 (**Exhibit I-6**).

²³⁵ See Kline, *Empty Hard Capsules: United States* at 70 (**Exhibit I-3**).

²³⁶ See Kline, *Empty Hard Capsules: United States* at 69 (**Exhibit I-3**); Affidavit of Michael Goetter at ¶¶ 8-10 (**Exhibit I-6**).

²³⁷ See Affidavit of Michael Goetter at ¶ 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, [

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

²³⁸ See Affidavit of Michael Goetter at ¶ 7 (**Exhibit I-6**).

²³⁹ See Affidavit of Michael Goetter at ¶ 8 (**Exhibit I-6**).

²⁴⁰ See Kline, *Empty Hard Capsules: United States* at 67 (**Exhibit I-3**).

²⁴¹ See Kline, *Empty Hard Capsules: United States* at 71 (**Exhibit I-3**); see also Affidavit of Michael Goetter at ¶¶ 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

²⁴² See Affidavit of Michael Goetter at ¶ 19 (Exhibit I-6).

²⁴³ See Affidavit of Michael Goetter at ¶ 19 (Exhibit I-6).

²⁴⁴ See Affidavit of Michael Goetter at ¶ 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).

²⁴⁶ *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.

²⁴⁷ *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).

²⁴⁸ *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).

²⁴⁹ *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 [

].²⁵⁰ [] 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.²⁵¹ Moreover, as explained in the 2023 Kline Report, the U.S. HEC market [

] in which [

].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

²⁵⁰ See Kline, *Empty Hard Capsules: United States* at 46 (Exhibit I-3).

²⁵¹ See Affidavit of Michael Goetter at ¶ 24 (Exhibit I-6).

²⁵² See Kline, *Empty Hard Capsules: United States* at 32 (Exhibit I-3).

²⁵³ See Affidavit of Michael Goetter at ¶¶ 23-24 (Exhibit I-6).

²⁵⁴ See Affidavit of Michael Goetter at ¶ 24 (Exhibit I-6).

²⁵⁵ See Affidavit of Michael Goetter at ¶ 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 [] 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 []

[]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

²⁵⁶ See Affidavit of Michael Goetter at ¶ 23 (**Exhibit I-6**).

²⁵⁷ See Kline, *Empty Hard Capsules: United States* at 32 (**Exhibit I-3**).

²⁵⁸ See Affidavit of Michael Goetter at ¶ 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.

²⁵⁹ 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**).

²⁶⁰ See Lonza, *Orange Book* at 22 (**Exhibit I-8**).

²⁶¹ See Affidavit of Michael Goetter at ¶ 18 (**Exhibit I-6**).

²⁶² See Affidavit of Michael Goetter at ¶ 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

²⁶³ See Port-of-Entry Import Data for the Subject Merchandise (**Exhibit I-76**).

²⁶⁴ See Affidavit of Michael Goetter at ¶ 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 2024.²⁶⁷ 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

²⁶⁵ See Affidavit of Michael Goetter at ¶¶ 15-16 (Exhibit I-6).

²⁶⁶ See Affidavit of Michael Goetter at ¶ 15 (Exhibit I-6).

²⁶⁷ See Monthly Import Data for the Subject Merchandise (January 2021 – June 2024) (Exhibit I-77).

²⁶⁸ See Affidavit of Michael Goetter at ¶ 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).

²⁷⁰ See Volume and Value of Subject Imports (**Exhibit I-48**).

²⁷¹ See Volume and Value of Subject Imports (**Exhibit I-48**).

²⁷² See Market Share Calculations (**Exhibit I-50**).

²⁷³ See Market Share Calculations (**Exhibit I-50**).

²⁷⁴ 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**).

²⁷⁷ 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).

²⁷⁹ See Underselling Analysis (**Exhibit I-51**).

²⁸⁰ 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.”²⁸³ 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.²⁸⁴ 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

²⁸¹ See Petitioner’s U.S. Operational and Financial Performance (**Exhibit I-87**); see also Market Share Calculations (**Exhibit I-50**).

²⁸² 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.²⁸⁶ 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.²⁸⁷ These declines in U.S. production and sales volumes are [

].²⁸⁸ Petitioner's net sales values have also declined, dropping from [] 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

²⁸⁶ See Petitioner's U.S. Operational and Financial Performance (**Exhibit I-87**); see also Market Share Calculations (**Exhibit I-50**).

²⁸⁷ See Petitioner's U.S. Operational and Financial Performance (**Exhibit I-87**); see also Market Share Calculations (**Exhibit I-50**).

²⁸⁸ See Affidavit of Michael Goetter at ¶ 27 (**Exhibit I-6**).

²⁸⁹ 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 [].²⁹³ All of this has been due to reduced demand for Petitioner's HECs as a result of competition from dumped and subsidized subject imports.

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

Fifth, 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

²⁹⁰ See Market Share Calculations (Exhibit I-50).

²⁹¹ See Market Share Calculations (Exhibit I-50).

²⁹² See Petitioner's U.S. Operational and Financial Performance (Exhibit I-87).

²⁹³ See Affidavit of Michael Goetter at ¶ 32 (Exhibit I-6).

²⁹⁴ 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	[			75.00%	]
Net Sales Values	[210,000,000				]
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	[				]
Operating Income	[	65,000,000			]
Gross Profit Margin	[			70.00%	]
Operating Profit Margin	[		40.00%		]

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.”²⁹⁷

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

].²⁹⁸ Indeed, as a result of the financial damage caused by subject imports, Petitioner [

].²⁹⁹

As Mr. Goetter attests in his affidavit: [

].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,

²⁹⁵ See Affidavit of Michael Goetter at ¶ 33 (Exhibit I-6).

²⁹⁶ See Affidavit of Michael Goetter at ¶ 33 (Exhibit I-6).

²⁹⁷ See Affidavit of Michael Goetter at ¶ 33 (Exhibit I-6).

²⁹⁸ See Affidavit of Michael Goetter at ¶ 34 (Exhibit I-6).

²⁹⁹ See Affidavit of Michael Goetter at ¶ 36 (Exhibit I-6).

³⁰⁰ See Affidavit of Michael Goetter at ¶ 36 (Exhibit I-6).

³⁰¹ See Affidavit of Michael Goetter at ¶ 35 (Exhibit I-6).

Petitioner has [

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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

³⁰² See Affidavit of Michael Goetter at ¶ 35 (Exhibit I-6).

³⁰³ 19 U.S.C. § 1677(7)(F)(i).

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.

For example, in India, Kline reports that [

]:

[

³⁰⁶ 19 U.S.C. § 1677(7)(F)(i)(I).

³⁰⁷ 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.

J.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

³⁰⁸ 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.

First, 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 [

].³¹¹ In China, Kline reports [

].³¹² In India, Kline reports that [

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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).

³¹⁰ See Lonza, *Orange Book* at 10 (**Exhibit I-8**).

³¹¹ See Kline, *Empty Hard Capsules: Brazil* at 67 (**Exhibit I-57**).

³¹² See Kline, *Empty Hard Capsules: China* at 65 (**Exhibit I-59**).

³¹³ 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 [

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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).³¹⁸ Construction of this facility—which will focus on HPMC HECs—is underway, with completion expected in 2025.³¹⁹ ACG plans for this new facility to have a

³¹⁴ See Lonza, *HEC Competitive Landscape Deep Dive Review: Tier 2 Indian & Chinese Suppliers* (June 2022) (“Lonza, *Indian & Chinese Suppliers*”) at 26 (**Exhibit I-78**).

³¹⁵ See Lonza, *Indian & Chinese Suppliers* at 26 (**Exhibit I-78**).

³¹⁶ See Lonza, *Indian & Chinese Suppliers* at 27 (**Exhibit I-78**).

³¹⁷ See Kline, *Empty Hard Capsules: China* at 69, 77 (**Exhibit I-59**).

³¹⁸ 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**).

³¹⁹ 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

³²⁰ 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**).

³²¹ See CareEdge Ratings, *ACG Associated Capsules Private Limited* (Dec. 7, 2023) at 2 (**Exhibit I-74**).

³²² See CareEdge Ratings, *ACG Associated Capsules Private Limited* (Dec. 7, 2023) at 2 (**Exhibit I-74**). Petitioner notes that the report at **Exhibit I-74** describes ACG's planned Maharashtra facility as an HPMC raw material production facility and its planned Dahej facility as an HEC manufacturing facility. However, news reports (such as the reports at **Exhibits I-79** and **I-80**) and market intelligence from [] indicate that the Maharashtra facility is the HPMC HEC facility and the Dahej facility is the HPMC raw material facility. See Lonza, *ACG Associated Capsules - Manufacturing Footprint* (**Exhibit I-81**); State-Level Expert Appraisal Committee, State Environment Impact Assessment Authority of Maharashtra, Environmental Clearance for ACG Cellulose Private Limited (**Exhibit I-82**); *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**).

³²³ See Lonza, *Indian & Chinese Suppliers* at 32 (**Exhibit I-78**).

³²⁴ See Natural Capsules Annual Report (2022-2023) at 1 (**Exhibit I-83**).

³²⁵ 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.”³²⁷ 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 [

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[

].³³¹ [

³²⁶ See Natural Capsules Annual Report (2022-2023) at 4, 7 (Exhibit I-83).

³²⁷ See Natural Capsules Annual Report (2022-2023) at 6 (Exhibit I-83).

³²⁸ See Natural Capsules Annual Report (2022-2023) at 27 (Exhibit I-83).

³²⁹ See Kline, *Empty Hard Capsules: India* at 77, 79 (Exhibit I-58).

³³⁰ See Kline, *Empty Hard Capsules: Vietnam* at 37, 38, 39, 42, 45, 50, 51, 57, 63, 66, 68 (Exhibit I-60).

³³¹ See Kline, *Empty Hard Capsules: Vietnam* at 37, 45, 66 (Exhibit I-60).

].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, [

].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.

³³² See Kline, *Empty Hard Capsules: Vietnam* at 37, 51, 57, 66 (**Exhibit I-60**).

³³³ See Kline, *Empty Hard Capsules: Vietnam* at 57, 58 (**Exhibit I-60**).

³³⁴ See Lonza Annual Report (2023) at 54 (**Exhibit I-70**).

³³⁵ 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**).

³³⁶ 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).

³³⁸ 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:

[

³⁴⁰ See Underselling Analysis (**Exhibit I-51**).

], {which
include Petitioner and Qualicaps}.³⁴¹

Kline also reported in 2023 that, in India, [

].³⁴² Furthermore, in Vietnam, [

].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 [

].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

³⁴¹ See Kline, *Empty Hard Capsules: United States* at 68 (Exhibit I-3).

³⁴² Kline, *Empty Hard Capsules: India* at 89, 92 (Exhibit I-58).

³⁴³ Kline, *Empty Hard Capsules: Vietnam* at 66 (Exhibit I-60).

³⁴⁴ 19 U.S.C. § 1677(7)(F)(i)(V).

³⁴⁵ 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 [

]."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:

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

³⁴⁶ See Market Share Calculations (Exhibit I-50).

³⁴⁷ See Affidavit of Michael Goetter at ¶ 33 (Exhibit I-6).

³⁴⁸ See Affidavit of Michael Goetter at ¶ 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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