4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1434]

Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act." When finalized, this draft guidance will describe the process that trading partners and stakeholders should use to request a waiver, exception, or exemption from certain requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and describe how FDA intends to review and decide such requests and determine FDA-initiated exceptions and exemptions. Additionally, when finalized, this draft guidance will describe how FDA intends to biennially review and renew waivers, exceptions, and exemptions.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-1434 for "Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal

Food, Drug, and Cosmetic Act; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket

number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Abha Kundi, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, drugtrackandtrace@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act." The Drug Supply Chain Security Act (DSCSA) was signed into law on November 27, 2013 (Title II of Pub. L. 113-54). The DSCSA outlines critical steps to build an electronic, interoperable system by 2023 that can identify and trace products as they are distributed in the United States. Section 202 of the DSCSA added section 582 to the FD&C Act

(21 U.S.C. 360eee-1), which sets forth trading partner requirements, including those related to product tracing, product identifiers, authorized trading partners, and verification. Section 582(a)(3)(A) of the FD&C Act directs FDA to establish processes by which: (1) an authorized trading partner (i.e., manufacturer, repackager, wholesale distributor, or dispenser) may request a waiver from certain requirements in section 582 if it would result in an undue economic hardship or for emergency medical reasons; (2) a manufacturer or repackager may request an exception to the section 582 requirements related to product identifiers if a product package is too small or otherwise unable to accommodate a label with sufficient space; and (3) FDA may determine other products or transactions shall be exempt from certain requirements in section 582.

Accordingly, this draft guidance describes these processes required by the law. Additionally, as required by section 582(a)(3)(B) of the FD&C Act, this draft guidance also includes a process for the biennial review and renewal of waivers, exceptions, and exemptions.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the process for waivers, exceptions, and exemptions from the requirements of section 582 of the FD&C Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44

U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

III. Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the FD&C Act

Under the draft guidance, a trading partner or stakeholder may request a waiver, exception, or exemption from the requirements of section 582 of the FD&C Act. FDA estimates that annually a total of approximately 20 waiver, exception, or exemption requests will be submitted to the Agency by approximately 20 trading partners or stakeholders. This estimate is based on communications the Agency has had with trading partners and stakeholders since the enactment of the DSCSA in 2013. FDA also estimates that it will take respondents an average of

40 hours to prepare and submit each request, including the time to submit any additional followup information that may be requested by FDA. FDA estimates that the total annual burden hours for submitting these requests are approximately 800 hours (see table 1, row 1).

Under the draft guidance, a recipient of a waiver, exception, or exemption should notify FDA whenever there is a material change in the circumstances that were the basis for the relief. In addition, FDA intends to biennially review waivers, exceptions, and exemptions that are longer than 2 years in duration as described in the draft guidance, and may ask the recipients to submit information to determine whether there has been a material change in the circumstances.

FDA estimates that annually it will receive approximately 1 notification or other information from approximately 1 respondent that there has or has not been a material change in the circumstances that warranted the waiver, exception, or exemption, and that each notification will take approximately 16 hours to prepare and submit to FDA. We estimate that the total annual burden hours for submitting this information to FDA are approximately 16 hours (see table 1, row 2).

Under the draft guidance, a trading partner may request that FDA renew a waiver, exception, or exemption that is of limited duration. This request should include a detailed statement justifying the continuance of the relief and the desired length of the extension. FDA estimates that annually it will receive approximately 1 renewal request from approximately 1 respondent, and that each request will take approximately 16 hours to prepare and submit to FDA. We estimate that the total annual burden hours for submitting these requests to FDA are approximately 16 hours (see table 1, row 3).

Table 1.--Estimated Annual Reporting Burden[1]

Waivers, Exceptions, and Exemptions from section 582 of the FD&C Act--Draft Guidance	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Requests to FDA for a Waiver, Exception, or Exemption	20	1	20	40	800
Notification to FDA of a Material Change in Circumstances Warranting the Waiver, Exception, or Exemption	1	1	1	16	16
Requests to FDA to Renew a Waiver, Exception, or Exemption	1	1	1	16	16
Total					832

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or https://www.regulations.gov.

Dated: May 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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