## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0192]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors With Interest in Exporting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by November 2, 2017.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0509. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors With Interest in Exporting—21 U.S.C. 371

*OMB Control Number 0910–0509—Extension*

The United States exports a large volume and variety of foods in international trade. For certain food products, foreign governments may require assurances from the responsible authority of the country of origin of an imported food that the processor of the food is in compliance with applicable country of origin regulatory requirements. With regard to U.S. milk products, FDA is the competent U.S. food safety authority to provide this information to foreign governments. FDA provides the requested information about processors in the form of lists, which are provided to the foreign governments and posted online at *https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm.*

Currently, FDA provides Chile, China, and the European Union (EU) with a list of U.S. milk product manufacturers/processors that: (1) Have expressed interest in exporting their products to these countries; (2) are subject to FDA's jurisdiction; and (3) are not the subject of a pending enforcement action (*i.e.,* an injunction or seizure or a pending warning letter).

FDA has published guidance documents for these countries under the authority of section 701(h) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)), which authorizes the Secretary of Health and Human Services (the Secretary) to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA.

The guidance documents explain what information manufacturers/processors should submit to FDA to be considered for inclusion on the lists and what criteria FDA intends to use to determine eligibility for placement on the lists. The guidance documents also explain how FDA intends to update the list and communicate any new information to the government that requested the list. Finally, the guidance documents note that the information is provided voluntarily by manufacturers/processors with the understanding that it will be posted on FDA's external Web site and communicated to, and possibly further disseminated by, the government that requested the list; thus, FDA considers the information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4).

Application for inclusion on each list is voluntary. However, some foreign governments may require inclusion on the list for acceptance of imported food. FDA recommends that U.S. manufacturers/processors that want to be placed on the export lists send FDA the following information: (1) Country to which the milk manufacturer/processor wants to export product; (2) type of milk product facility; (3) the Food Facility Registration Module number (the information collected by this module is approved under OMB control number 0910–0502); (4) name and address of the firm and the manufacturing plant; (5) name, telephone number, and email address of the contact person; (6) list of products divided into three categories: Presently shipped, ready to ship, and available for shipment in the next 3 years; (7) identities of Agencies that inspected the plant; (8) date of last inspection, plant number, and copy of last inspection notice; and (9) if other than an FDA inspection, copy of last inspection report.

We request that this information be updated every 2 years.

We use the information submitted by firms to determine their eligibility for placement on the export lists, which are published on our Web site. The purpose of the lists is to help foreign governments in their determinations of which U.S. milk product manufacturers and processors are eligible to export to their respective countries.

FDA has recently developed an electronic registry system (Form FDA 3972) that allows milk product manufacturers and processors to electronically send a request to FDA to be included on the export lists. Manufacturers and processors that prefer to submit a paper request in a format of their own choosing will still have the option to do so. Electronic Form FDA 3972 collects the same information as is currently collected via the existing paper-based process. Draft screenshots of Form FDA 3972 and instructions are available at *https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm496929.htm* and is entitled ''Dairy Listing Module.''

*Description of Respondents:* Respondents to this collection of information include U.S. milk product manufacturers/processors subject to FDA jurisdiction that wish to export to certain foreign countries that require inclusion on export lists.

In the **Federal Register** of June 15, 2017 (82 FR 27485), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received three comments, however, they were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| New requests to be placed on the lists | 2,000 | 1 | 2,000 | 1 | 2,000 |
| Biennial update | 2,000 | 1 | 2,000 | 0.5 (30 minutes) | 1,000 |
| Occasional updates | 200 | 1 | 200 | 0.5 (30 minutes) | 100 |
| Total | | | | | 3,100 |

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

FDA bases its estimate on the number of manufacturers/processors that have submitted new written requests, biennial updates, and occasional updates over the past 10 years. The estimate of the number of burden hours it will take a manufacturer/processor to gather the information needed to be placed on the list or update its information is based on FDA's experience with manufacturers/processors submitting similar requests. FDA believes that the information to be submitted will be readily available to manufacturers/processors. This collection is also incorporating information collected to maintain lists of eligible exporters of dairy products who wish to export to the EU from OMB control number 0910–0320, ''Request for Information from U.S. Processors that Export to the European Community.''

FDA estimates that 2,000 firms will average 60 minutes (1 hour) to submit new requests for inclusion on the list, 2,000 firms will average 30 minutes (0.5 hour) to update their information every 2 years, and 200 firms will average 30 minutes (0.5 hour) to occasionally update their information in this system. We also believe that submission via the electronic registry system will not affect the burden estimates. An electronic registry will enhance the ability of firms to more efficiently request inclusion on export lists. FDA calculates, therefore, that the total burden for this collection is 3,100 hours ((2,000 × 1) plus (2,000 × 0.5) plus (200 × 0.5)).

Dated: September 28, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–D–5767]**

### Abbreviated New Drug Applications for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of Recombinant Deoxyribonucleic Acid Origin; 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 ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin.'' The Federal Food, Drug, and Cosmetic Act (FD&C Act) permits any person to submit to the FDA an abbreviated new drug application (ANDA) to seek approval to market a generic version of a previously approved drug product. This draft guidance is intended to assist potential applicants in determining when an application for a synthetic peptide drug product (specifically glucagon, liraglutide, nesiritide, teriparatide, and teduglutide) that refers to a previously approved peptide drug product of recombinant deoxyribonucleic acid (rDNA) origin should be submitted as an ANDA rather than as new drug application (NDA).

**DATES:** Submit either electronic or written comments on the draft guidance by December 4, 2017 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–2017–D–5767 for ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin.'' 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.