



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1207]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining a List of U.S.

Manufacturers/Processors of Feed Additives, Premixes, Compound Feed, Distillers' Dried Grains, and Distillers' Dried Grains with Solubles for Use with Animals with Interest in Exporting to The People's Republic of China

AGENCY: Food and Drug Administration, Health and Human Services (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: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0884. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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 a List of U.S. Manufacturers/Processors of Feed Additives, Premixes, Compound Feed, Distillers' Dried Grains, and Distillers' Dried Grains with Solubles for Use with Animals with Interest in Exporting to The People's Republic of China

OMB Control Number 0910-0884

This information collection request allows FDA to include respondents who are U.S. manufacturers/processors of feed additives, premixes, compound feed, distillers' dried grains, and distillers' dried grains with solubles (hereinafter, "manufacturers/processors" of "covered products") on a list of those who wish to export their products to The People's Republic of China (China). On January 15, 2020, the United States and China entered into an Economic and Trade Agreement (the Agreement) which, among other things, will streamline the procedures for, and improve the efficiencies of, the exportation of U.S. covered products to China. These provisions of the Agreement are intended to facilitate trade between the two countries to better meet the demand for U.S. animal feed products in China and to promote the development of animal husbandry in China. Since the timing of the Agreement did not allow for publication of a 60-day notice under the PRA in advance of its implementation, FDA requested and OMB granted emergency review under 5 CFR 1320.13 of a new information collection request.

In the *Federal Register* of April 16, 2020 (85 FR 21242), subsequent to implementation under the emergency clearance, we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Respondents: Manufacturing/processing facilities of covered products interested in exporting animal feed to China.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§ 1.101(b)(1); Request for list placement to export to China--data elements demonstrating that product meets the foreign purchaser's specifications	450	1	450	0.083	38

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

We have revised our burden table. In the 60-day notice published on April 16, 2020, the burden table identified types of respondents. Here we are clarifying that the information being collected is a request from those respondents to be placed on a list. By requesting to be placed on the list, respondents agree to disclose data elements, as agreed upon by the U.S. government and China, that demonstrate the product meets acceptable entry criteria. Since establishing the collection, we have 197 facilities on the list to date. There were fewer emails received, as some of the companies registered multiple facilities in a single email.

Based on our experience with a similar information collection, upon requesting to be placed on the list, data elements that may be provided to China include the facility name, street address, city, State, and ZIP code of U.S. manufacturers and processors of covered products, who want to be included on the list sent to China.

Manufacturers of these products must currently register with FDA consistent with 21 CFR part 1, subpart H. Therefore, we believe burden associated with this collection should be minimal, but we welcome specific feedback in this regard.

Dated: July 30, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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