United States Food and Drug Administration

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 No. 0910-NEW

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

   This information collection supports a Food and Drug Administration (FDA, us or we) program by which respondents may be included on a list of U.S. manufacturers/processors of covered products that wish to export their products to 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.

   Pursuant to the agreement, we have to provide a list of U.S. manufacturers and processors of feed additives, premixes, compound feed, distillers' dried grains, and distillers dried grains with solubles for use with animals (hereinafter, "manufacturers/processors" of "covered products") that wish to export their products to the People's Republic of China (China).

   In order to compile the list, registered manufacturers need to send us a request and authorization to include a facility on the list. FDA currently does not have approval under the PRA to collect this information. We therefore request OMB approval of this new information collection as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

   The information received will allow the Agency to compile the list of manufacturers/processers that wish to export their products to China.

   Description of Respondents: Respondents include U.S. manufacturers and processors of feed additives, premixes, compound feed, distillers' dried grains, and distillers dried grains with solubles for use with animals that wish to export their products to the People's Republic of China.

3. Use of Improved Information Technology and Burden Reduction

   The information requested will be submitted by requestors via email.

4. Efforts to Identify Duplication and Use of Similar Information

   We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

   This collection carries the same burden for small or large firms.

6. Consequences of Collecting the Information Less Frequently

   If the collection is not conducted, the list as required by the Trade Agreement will not be able to be compiled.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   The Food and Drug Administration (FDA or we) is requesting emergency processing under 5 CFR § 1320.13 of a new information collection request (ICR). We are seeking emergency processing for the following reasons:

   a. The collection of information is essential to FDA's mission. As the competent authority recognized by China with respect to FDA-regulated foods, including animal feeds, FDA helps facilitate international trade of such products. With respect to the collection of information at issue, we intend to facilitate trade by establishing and maintaining a list of U.S. manufacturers/processors that are interested in exporting the covered products to China and that meet the requirements of the Agreement. Specifically, under the Agreement, FDA intends to include on the export list those manufacturers/processors over which FDA has regulatory oversight and can verify that these facilities are registered with FDA per section 415 of the Federal Food, Drug, and Cosmetic Act. The information collection is critical for FDA to meet the U.S. government's obligation under this agreement and to facilitate trade of these covered products to China. The collection of information is thus essential to the mission of the agency under § 1320.13(a)(1)(ii).

   b. FDA cannot reasonably comply with the normal clearance procedures. On January 15, 2020, the United States and the People's Republic of China entered into an Economic and Trade Agreement. This Agreement goes into effect on Friday, February 14, 2020. Pursuant to the agreement, we have to provide a list. In order to compile the list, manufacturers need to send us a request and authorization to include a facility on the list. FDA currently does not have approval under the PRA to collect this information. The collection of information is needed in a shorter time than standard processing time would allow for. Following normal clearance procedures will result in a prolonged delay in FDA's ability to receive the information from U.S. exporters necessary for the agency to prepare the list of the covered products pursuant to the Agreement. Thus, under § 1320.13(a)(2)(ii) an unanticipated event has occurred, and, under § 1320.13(a)(2)(iii), the use of normal clearance procedures is reasonably likely to prevent the collection of information for an indeterminate length of time. Accordingly, FDA requests that OMB authorize emergency processing of FDA's new ICR.

9. Explanation of Any Payment or Gift to Respondents

   We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

This ICR does not collect personally identifiable information (PII) or information of a personal nature. Information collected is firm name, facility name, street address, city state, and zip code. This information collection supports a Food and Drug Administration program by which respondents may be included on a list of U.S. manufacturers/processors of covered products that wish to export their products to China. In order to compile the list, registered manufacturers need to send us a request and authorization to include a facility on the list. In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

The total annual hours is rounded to 38. FDA estimates the burden of this collection of information as follows:

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

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
U.S. manufacturers/ processors of covered products	450	1	450	.083	37.50

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

12b. Annualized Cost Burden Estimate

We estimate that the average hourly wage for respondents is equivalent to a GS-11-7 level in the locality pay area of Washington-Baltimore in 2019, approximately $40.01/hour. Increasing this wage by 30% to account for overhead costs ($12.00), FDA estimates the average hourly cost to respondents to be $52.01/hour. The overall estimated cost incurred by the respondents is $1,950.38 (37.50 burden hours x $52.01/hr = $1,950.38).

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

We estimate that it will take .25 hour (15 minutes) to review and validate each request. The annualized cost to the Federal government for the review and validation of the requests to be $XXX. We estimate the average hourly wage for personnel to review and validate a

submission to be at the GS-11 level in the locality pay area of Washington-Baltimore in 2020, approximately $34.51/hour. The estimated annualized cost to the Federal government is $3,882.38 (0.25 hours x 450 requests x $34.51/hr = $3,882.38).

15. Explanation for Program Changes or Adjustments*

    This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

    We have no plans to tabulate and publish information from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.