UNITED STATES FOOD & DRUG ADMINISTRATION

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. 0910-0884

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

Food and Drug Administration (FDA, the agency, us or we) general enforcement regulations in 21 CFR part 1 govern the export of FDA-regulated products. In accordance with the regulations, *"[p]ersons exporting an article under section 801(e)(1) of the act or an article otherwise subject to section 801(e)(1) of the act shall maintain records ... demonstrating that the product meets the requirements of section 801(e)(1) of the act,*" and that such records, "*must contain sufficient information to match the foreign purchaser's specifications to a particular export.*" (See 21 CFR 1.101(b); information collection associated with 21 CFR 1.101(d) in conjunction with drugs, biological products, and devices exported under section 802 of the act is covered under OMB control no. 0910-0482.) In addition, regulations in part 1, subpart H (21 CFR §§ 1.225-1.245) provide that anyone engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, including animal food, must register with FDA unless a waiver has been granted. Information collection provisions applicable to 21 CFR part 1, subpart H are currently approved under OMB control no. 0910-0502. Consistent with 21 CFR 1.232, registration data provided to FDA by respondents includes contact information, facility information, and various pieces of product information depending on requirements applicable to the product.

In this request we are seeking approval for information collection associated with the establishment and maintenance of a list of manufactures of feed additives, premixes, compound feed, distillers' dried grains, and distillers' dried grains with solubles (hereinafter, "*manufacturers/processors*" of "*covered products*") registered with FDA who wish to export covered products to The People's Republic of China. On January 15, 2020, the United States and China entered into an Economic and Trade Agreement (the Agreement) which, among other things, is intended to streamline the procedures for, and improve the efficiencies of, exporting covered products to China. Inclusion on the list is also intended to facilitate trade of the covered products by allowing more expeditious identification of relevant data. In this way we can help better meet the demand for U.S. animal feed products in China and promote the development animal husbandry. Because we expect that the relevant data to be included on the list is already retained by respondents in satisfying domestic requirements as well as business operational needs, we believe minimum burden will be incurred.

Accordingly we request OMB approval of the information collection provisions associated with establishing a list of manufacturers of covered products who have interest in trading with China, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use respondent requests to be placed on the list to verify that respondents want to be [or want facility information to be] included and to ensure the accuracy of data to be disclosed. By requesting to be placed on the list, respondents agree to disclose relevant data elements, as agreed upon by the U.S. government and China, that demonstrate a covered product meets acceptable foreign entry criteria.

3. Use of Improved Information Technology and Burden Reduction

At this time, the information collection is completed by email. As resources enable us to enhance and integrate existing agency information systems to accommodate the new information collection, we will consider ways to more efficiently produce and maintain the list.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. We have a related information collection approved under OMB control no. 0910-0509 regarding the establishment and maintenance of a similar list for human foods. Upon further evaluation of the program we will consider whether combining the information collections is appropriate.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection poses undue burden on small entities. At the same time, we provide assistance to small businesses through resources on our website at www.fda.gov, including small entity compliance guidance on food facility registration.

6. Consequences of Collecting the Information Less Frequently

We intend to provide quarterly updates to China in accordance with the terms of the Trade Agreement.

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

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

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

We published a 60-day notice for public comment in the *Federal Register* of April 16, 2020 (85 FR 21242). Although no comments were received, in our 30-day notice of August 6, 2020 (85 FR 47796) we revised our table to better clarify the nature of the information collection.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected. Information collected includes firm name, facility name, and address and we have determined that a Privacy Statement is not required under The Privacy Act of 1974.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

We estimate the burden of the information collection as follows:

12a. Annualized Hour Burden Estimate:

21 CFR; IC 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	.083 (5 mins.)	38

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

Based on the number of annual facility registrations there is a potential for several hundred respondents to the information collection. Since establishing the collection, we have received requests for 197 facilities to be placed on the list. We assume it takes 5 minutes (.0833 hour) to compose and submit the requisite e-mail. Based on this experience and our experience with similar information collection, we estimate 450 annual requests and 38 burden hours.

12b. Annualized Cost Burden Estimate:

Type of Respondent	Burden Hours	Hourly Wage Rate	Total Respondent Costs
Executive Secretary[1]	38	39.32	$1,494.16

[1] May 2019 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics, Executive Secretaries 43-601. (https://www.bls.gov/oes/current/oes436011.htm) $30.25 hourly wage plus 30% adjusted for benefits.

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

Assuming we allocate one FTE to review and validate submissions, factor a wage rate of $41.37 (current GS-12/1 wage rate in the Washington DC Metropolitan Area based on current data available at www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/) by the annual hourly reporting burden, our estimate of the annual cost to the Federal government for the information collection is $9,308.25 (450 x .50 x $41.37 = $9,308.25).

15. Explanation for Program Changes or Adjustments*

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA has no such plans for the 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.