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

Request for Emergency Processing to Approve the Collection of Information from U.S. Manufacturers/Processors of Feed Additives, Premixes, Compound Feed, Distillers' Dried Grains, and Distillers' Dried Grains with Solubles with Interest in Exporting to The People's Republic of China

The Food and Drug Administration (FDA or we) is requesting emergency processing under 5 CFR § 1320.13 of a new information collection request (ICR). This ICR supports an agency program by which respondents may be included on 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). 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.

If certain conditions are met, an agency head or designee may request expedited OMB review of an ICR, also known as an "emergency" review. OMB may grant expedited review if the collection is essential to the mission of the agency, clearance is needed sooner than the normal timeframe, and the agency cannot reasonably comply with the normal clearance procedures of the Paperwork Reduction Act of 1995 (the PRA) because: "(i) public harm is reasonably likely to result if normal clearance procedures are followed; (ii) an unanticipated event has occurred; or (iii) the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed" (5 CFR § 1320.13(a)(2)). When OMB expedites review, OMB acts promptly to review the ICR through a suitably streamlined process, consistent with the purposes of the PRA. For example, OMB may modify—or, if necessary, waive—the public comment requirements. Emergency clearance may be granted for a maximum of six months.

We are seeking emergency processing for the following reasons:

1. 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).

2. 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, entitled "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 China." FDA is submitting with this request a copy of the Agreement that was signed on January 15, 2020. **We are requesting OMB approval or disapproval as soon as OMB deems practicable.**

Steven Solomon -S Digitally signed by Steven Solomon -S
Date: 2020.02.10 11:22:45 -05'00'

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