4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1657]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Drug Product Manufacturing, Processing, and Packing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 Comment" or by using the search function. The title of this information collection is "Survey of Drug Product Manufacturing, Processing, and Packing Facilities." 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.

Survey of Drug Product Manufacturing, Processing, and Packing Facilities--21 CFR Parts 210 and 211

OMB Control Number 0910-NEW

FDA has the responsibility to regulate the safety, as well as the efficacy and quality, of drugs in the United States. Under the Food and Drug Administration Safety and Innovation Act, enacted in 2012, the term current good manufacturing practice (CGMP) includes the implementation of oversight and controls over the manufacturing, processing, and packing of drugs to ensure quality, including managing the risk of, and establishing the safety of, raw materials used in the manufacture of drugs. The safety and availability of drugs can be affected by raw material suppliers, the material supply chain, and the facility's controls over raw material quality. Risk management enables manufacturers to make proper choices and ensure the continued suitability of these materials and supply chains. The Agency needs to better understand how manufacturers, processors, and packers of drug products approach managing risks related to components, containers, and closures as well as the supply and distribution chains between the producers of raw materials and drug product manufacturers, processors, and packers. Such information will allow FDA to examine the potential economic impact of changes to regulations that govern the manufacturing, processing, and packing of drugs.

In the *Federal Register* of September 18, 2020 (85 FR 58370), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

This is a one-time information collection, the primary purpose of which is to collect industry-wide data on how facilities that manufacture, process, and pack drug products for use in humans and/or animals ensure the quality of their operations, including their current risk

management approaches and practices for ensuring the quality and suitability of the drug components, containers, and closures that they use. FDA intends to use this information to inform its economic analyses of potential updates to CGMPs for human and animal drug product manufacturing, processing, and packing facilities under 21 CFR parts 210 and 211. Survey respondents will be contacted by email or, if necessary, by regular mail. Respondents will be able to take the survey online or, if requested, they can return a hard copy by mail. FDA estimates the maximum burden of this collection of information as follows:

Table 1.--Estimated Burden Hours for One-Time Data Collection[1]

Type of Respondent/Facility	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Group 1: Facilities in United States engaged in drug manufacturing (in addition to other possible activities)	394	1	394	1.1	433
Group 2: Facilities in United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.)	333	1	333	0.75 (45 minutes)	250
Group 3: Facilities outside United States engaged in drug manufacturing (in addition to other possible activities)	407	1	407	2.20	895
Group 4: Facilities outside United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.)	261	1	261	1.5	392
Total	1,395		1,395		1,970

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

Burden hours are based on pretests of the survey and interviews with industry representatives and reflect the time required by each type of respondent to read the survey invitation and instructions and complete the survey questions. The total estimated one-time burden hours are 1,970.

Dated: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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