4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4735]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Safety Labeling Changes--Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, 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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0734. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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.

Safety Labeling Changes--Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0734--Extension

Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(o)(4)) authorizes FDA to require and, if necessary, order labeling changes if FDA becomes aware of new safety information that it believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). Section 505(o)(4) of the FD&C Act applies to prescription drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application under section 505(j) of the FD&C Act if the reference listed drug with an approved NDA is not currently marketed. Section 505(o)(4) establishes time frames by which application holders must submit, and FDA staff must review, information necessary to ensure timely and appropriate labeling changes. To communicate how we implement these provisions we developed the guidance entitled "Guidance for Industry: Safety Labeling Changes--Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act," which provides instruction on: (1) a description of the types of safety labeling changes that ordinarily might be required; (2) how FDA plans to determine what constitutes new safety information; (3) the procedures involved in requiring safety labeling changes, and (4) enforcement of the requirements for safety labeling changes. The guidance is currently posted to

the docket and available on FDA's website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-labeling-changes-implementation-section-505o4-federal-food-drug-and-cosmetic-act.

As explained in the guidance, we send application holders a notification letter when safety labeling changes are required. Under section 505(o)(4)(B) of the FD&C Act, the application holder must respond to our notification by either submitting a labeling supplement, or a rebuttal statement explaining why it believes the labeling change is unwarranted. Based on our experience to date with safety labeling changes requirements under section 505(o)(4) of the FD&C Act, we estimate that 36 application holders will elect to submit 1 rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, the guidance explains that labeling prepared in response to a safety labeling change notification should be available on the application holder's website within 10 calendar days of approval. We estimate that 351 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

In the *Federal Register* of February 12, 2019 (84 FR 3461), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received. The comment offered general support for the information collection, provided certain statistical details regarding potential respondents, encouraged utilization of electronic and/or digital technology where possible, and offered a related topic for which additional guidance might be useful. We appreciate the comment and will continue to consider the suggestions provided. At the same time, it was not suggested that we make changes to our burden estimate, which remains as follows:

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Rebuttal statement	36	1	36	6	216

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

Table 2.--Estimated Annual Third-Party Disclosure Burden[1]

Type of Submission	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Posting approved labeling on application holder's website	351	1	351	4	1,404

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

Since last OMB review and approval, we have adjusted our estimated annual number of respondents downward by 62. The decrease reflects that we have issued fewer safety labeling notifications, and thus fewer postings are required and fewer rebuttals are expected.

Dated: June 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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