4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0341]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

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 0910-0638. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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.

Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices--(OMB Control Number 0910-0638)--Extension

The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. As a result of this provision, the guidance explains the importance of making available to health care providers the most current information regarding susceptibility test interpretive criteria for antibacterial drug products. To address concerns about antibacterial drug product labeling with out-of-date information on susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods, the guidance describes procedures for FDA, applications holders, and antimicrobial susceptibility testing device manufacturers to ensure that updated susceptibility test information is available to health care providers. Where appropriate, FDA will identify susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods by recognizing annually, in a Federal Register notice, standards developed by one or more nationally or internationally recognized standard development organizations. FDA recognized standards will be available to application holders of approved antibacterial drug products for updating their product labeling.

Application holders can use one of the following approaches to meet their responsibilities to update their product labeling under the guidance and FDA regulations: Submit a labeling supplement that relies upon a standard recognized by FDA in a Federal Register notice or submit a labeling supplement that includes data supporting a proposed change to the microbiology information in the labeling. In addition, application holders should include in their annual report an assessment of whether the information in the "Microbiology" subsection of their product labeling is current or whether changes are needed. This information collection is already approved by OMB under control numbers 0910-0572 (the requirement in 21 CFR 201.56(a)(2) to update labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading) and 0910-0001 (the requirement in 21 CFR 314.70(b)(2)(v) to submit labeling supplements for certain changes in the product's labeling and the requirement in 21 CFR 314.81(b)(2)(i) to include in the annual report a brief summary of significant new information from the previous year that might affect the labeling of the drug product).

In addition, under the guidance, if the information in the applicant's product labeling differs from the standards recognized by FDA in the Federal Register notice, and the applicant believes that changes to the labeling are not needed, the applicant should provide written justification to FDA why the recognized standard does not apply to its drug product and why changes are not needed to the "Microbiology" subsection of the product's labeling. This justification should be submitted as general correspondence to the product's application, and a statement indicating that no change is currently needed and the supporting justification should be included in the annual report. Based on our knowledge of the need to update information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use, and our experience with

the FDAAA requirement and the guidance recommendations during the past 16 months, we estimate that, annually, approximately two applicants will submit the written justification described previously and in the guidance, and that each justification will take approximately 16 hours to prepare and submit to FDA as general correspondence and as part of the annual report.

In the Federal Register of April 7, 2014 (79 FR 19099), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. The comment expressed support for FDA's efforts to review updated breakpoints published by appropriate nationally or internationally recognized standard setting bodies, and then determine whether to recognize these recommendations in an annual Federal Register notice based upon the best available scientific and clinical evidence. The comment also urged FDA and outside organizations to prioritize the harmonization of breakpoints, taking into account possible differences in doses and dosing schedules used in different parts of the world. The comment also expressed support for the provisions in the Antibiotic Development to Advance Patient Treatment (ADAPT) Act, H.R.3742. The comment said that the ADAPT Act would direct FDA to publish quarterly on its Web site new or updated breakpoints set by an appropriate standard setting organization and recognized by the Agency. The comment said it would also support additional statutory changes to remove breakpoint information from the paper labeling of antibacterial drugs and establish a scheme whereby FDA may clear antimicrobial susceptibility testing devices that incorporate breakpoints that have been set by an outside standard setting body and recognized by the FDA.

FDA appreciates the comment and we will continue our efforts on updating information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use.

FDA estimates the burden of this collection of information 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
Justification Submitted as General Correspondence and in the Annual Report	2	1	2	16	32

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

Dated: October 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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