4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1999-D-4079]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements

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 (PRA).

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-NEW and title "Guidance for Industry on Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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: Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements

OMB Control Number 0910-NEW

This information collection request supports the Agency guidance entitled, "Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements." The guidance discusses the requirement for prescription drug promotional labeling and advertisements to include the established name in conjunction with the proprietary name, and explains FDA recommendations that:

- Firms should include the established name at least once per page or spread where the proprietary name most prominently appears.
- The established name should be placed either directly beside or below the proprietary name without any intervening matter.
- The size of the established name should be at least half the size of the presentation of the proprietary name wherever the established name is required.
- For superimposed text that is equivalent to a headline or tagline, the established name should be presented alongside the most prominent presentation of the proprietary name in audiovisual promotional materials (promotional labeling and broadcast advertisements).

- For electronic and computer-based promotion, the established name should accompany the proprietary name at least once per web page, and this should generally be where the proprietary name most prominently appears on the web page.

Thus, the guidance recommends that firms disclose certain information to others when fulfilling the product name placement requirements. This third-party disclosure constitutes a collection of information under the PRA.

In the *Federal Register* of November 20, 2013 (78 FR 69691), FDA published a 60-day notice requesting public comment on the proposed collection of information and the estimated annual burden for third party disclosure. In response to that notice FDA received no comments in response to the proposed collection of information.

As explained below, table 1 provides an estimate of the annual third-party disclosure burden associated with this collection of information. The placement, size, prominence, and frequency of the proprietary and established names for human prescription drugs, including prescription biological products, and animal prescription drugs are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h); 202.1(b), (c) and (d), and 610.62). Using calendar year 2015 data, FDA estimates that, for prescription human and animal drugs and biological products, approximately 407 firms disseminate approximately 104,358 advertisements and promotional pieces each year. We further estimate that the burden hours associated with the regulatory requirements would be approximately 3 hours per disclosure.

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

Guidance Recommendations	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure (in hours)	Total Hours
Disclosures Related to Product Name Placement, Size, and Prominence	407	256.4	104,358	3	313,074

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

Dated: December 6, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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