4161-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0387]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommended Content of Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling and Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities

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: 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 Comments" or by using the search function. The OMB control numbers for the collections of information are 0910-0856 and 0910-0857. 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, 10A-12M, 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.

I. Medical Product Communications That Are Consistent With the FDA-Required Labeling--Questions and Answers

OMB Control Number 0910-0856--Extension

This information collection supports the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's implementing regulations that govern drug and device labeling and prescription drug and restricted device advertising. Section 502(a) of the FD&C Act (21 U.S.C. 352(a)) specifies that a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular, and that labeling may be considered misleading if it fails to reveal material facts about the product being promoted, including facts that are material in light of the representations made in a promotional piece (section 201(n) of the FD&C Act (21 U.S.C. 321(n))). Similarly, under sections 201(n) and 502(n) of the FD&C Act and FDA's implementing regulations (21 CFR 202.1(e)(5)(i) and (iii)), an advertisement for a prescription drug must not be false or misleading with respect to side effects, contraindications, or effectiveness, or fail to reveal material facts about the product being advertised, including facts that are material in light of the representations made in a promotional piece. The FD&C Act also specifies that restricted device advertisements must not be false or misleading (section 502(q)(1)) and must reveal facts that are material about the product being advertised (section 201(n)).

To assist respondents with drug and device labeling requirements and prescription drug and restricted device advertising, we developed the guidance for industry entitled "Medical Product Communications That Are Consistent With the FDA-Required Labeling--Questions and Answers" (June 2018) (medical product communications guidance), available at https://www.fda.gov/media/133619/download. This medical product communications guidance includes recommendations that firms consider when developing "*consistent with the FDA-required labeling* (CFL)" presentations in their labeling and advertising materials to help ensure

the presentations are not false or misleading in violation of the FD&C Act and FDA's implementing regulations. The guidance also describes FDA's thinking when examining the consistency of a firm's product communications with that product's own FDA-required labeling.

As explained in the guidance, if a firm communicates information that is not contained in its product's FDA-required labeling but that is determined to be consistent with the FDA-required labeling, FDA does not intend to rely on that communication to establish a new intended use that is different from the use or uses for which the product is legally marketed. Establishing a product's intended uses is an element in establishing certain violations under the FD&C Act and Public Health Service Act. Firms' communications about their products that are consistent with the products' FDA-required labeling but that are false or misleading may subject a firm to enforcement action under the FD&C Act. Thus, the guidance not only describes FDA's thinking on communications that are consistent with the FDA-required labeling, but also provides general recommendations intended to help firms comply with requirements in the FD&C Act and FDA's implementing regulations for conveying information that is consistent with the FDA-required labeling in a truthful and non-misleading way. The medical product communications guidance recommends that firms accurately represent in the communications any study results or other data and information that are relied upon to support a firm's CFL promotional communication. Other recommendations include the clear and prominent disclosure of aspects of study design and methodology that are material for audiences to accurately interpret the information being presented (e.g., type of study, study objectives, product dosage and use regimens, control or controls used, patient population studied), as well as material limitations related to the study design, methodology, and results. Also, the guidance recommends that firms accurately characterize and contextualize the relevant information about the product, including by disclosing unfavorable or inconsistent findings. In addition, the guidance recommends that firms disclose material contextual information from the FDA-required labeling in these

communications, such as data and information from studies in the FDA-required labeling that are relevant to the data or information presented in the CFL promotional communication.

The recommendations will help ensure that health care professional and consumer audiences receive truthful information about the benefits and risks of drugs and devices in firms' CFL promotional communications and that material contextual information is included in these communications so that audiences are not misled. Accurate information helps these audiences know whether drugs or devices may be appropriate for them or their patients and know what they can expect to experience when prescribing or using these products.

In the *Federal Register* of May 10, 2021 (86 FR 24868), we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; one appearing to question the effectiveness of the information collection and the other offering its support. Neither comment suggested FDA revise its estimate of the attendant information collection.

We estimate the burden of this collection of information as follows:

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

Information Collection Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Recommended information to be included when firms choose to disseminate communications that are consistent with the FDA-required labeling	324	30	9,720	4	38,880

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

Since our last request for OMB approval, we have made no adjustments to the currently approved burden estimate.

II. Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities

OMB Control Number 0910-0857--Extension

This information collection also supports implementation of section 502(a) of the FD&C Act and applicable Agency regulations. Section 502(a)(1) of the FD&C Act provides that a drug

or device is deemed to be misbranded "[i]f its labeling is false or misleading in any particular." Under longstanding FDA practice and FDA's statute and regulations, and under case law, *labeling* encompasses more than merely the label of the drug, but extends to other written, printed, or graphic matter "accompanying such article" (section 201(m) of the FD&C Act; see also 21 CFR 1.3(a)). Section 502(a) of the FD&C Act also includes a provision about communication of health care economic information (HCEI) to payors through labeling or advertising. To assist respondents in this regard, we developed the guidance for industry and review staff entitled "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities--Questions and Answers" (June 2018) (drug and device communications guidance), available at https://www.fda.gov/media/133620/download.

This drug and device communications guidance includes recommendations regarding information firms should include in HCEI for prescription drugs if they choose to disseminate such materials (HCEI materials) to payors, in accordance with section 502(a) of the FD&C Act. Specifically, if a manufacturer communicates HCEI for approved prescription drugs (including biological products that also meet the definition of *drug* under the FD&C Act and approved or cleared medical devices (collectively referred to as *medical products*)) to payors, FDA recommends that firms include in HCEI materials disseminated to payors information about: (1) various aspects of study design and methodology of an economic analysis (i.e., type of analysis, modeling technique, patient population, perspective or viewpoint, treatment comparator, time horizon, outcome measures, cost estimates, and assumptions); (2) factors that limit generalizability of an economic analysis; limitations to an economic analysis; and (3) sensitivity analyses, if applicable, to allow for informed decision making by payors.

Furthermore, FDA recommends that firms include other information when disseminating HCEI materials, as applicable, to provide a balanced and complete presentation. Such information includes a statement of the FDA-approved indication of the drug and a copy of the most current FDA-approved labeling. Under section 502(a) of the FD&C Act, firms must also

include a conspicuous and prominent statement to describe any material differences between the HCEI and the FDA-approved labeling. HCEI materials should also disclose whether certain studies or data sources were omitted from an economic analysis and how the omission of those studies or data sources may alter the conclusions presented in the analysis. Moreover, FDA recommends that HCEI materials disclose important risk information associated with the approved use of the drug, and pursuant to section 502(a) of the FD&C Act, HCEI materials must disclose any additional risk information related to assumptions that vary from the approved labeling. In addition, HCEI materials should disclose potential financial or affiliation biases to the extent reasonably known by firms at the time of dissemination.

The drug and device communications guidance provides similar recommendations for HCEI materials disseminated to payors about approved or cleared devices.

If firms choose to make communications to payors about unapproved products or unapproved uses of approved or cleared products, FDA recommends that firms include a clear statement with their communications that the product or use is not approved or cleared and that the safety or effectiveness of the product or use has not been established.

In the *Federal Register* of May 10, 2021, we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; one appearing to question the effectiveness of the information collection and the other offering its support. Neither comment suggested FDA revise its estimate of the attendant information collection.

We estimate the burden of this collection of information as follows:

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

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved prescription drugs	430	10.465	4,500	20	90,000

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

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved or cleared devices	236	10	2,360	20	47,200
Recommended information to be included when firms choose to disseminate information about unapproved products or unapproved uses of approved or cleared products	717	2	1,434	0.5 (30 minutes)	717
Followup information to payors regarding previously communicated information about unapproved products or unapproved uses of approved or cleared products	359	2	718	2	1,436
Total			9,012		139,353

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

We have adjusted the estimate of burden we associate with the information collection recommendations in the guidance to reflect an increase of 2,000 hours and 100 responses annually.

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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