Dated: January 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1307]

Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers; Draft Guidance for Industry and Review Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and review staff entitled ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.'' This draft guidance provides answers to common questions regarding the communication of health care economic information (HCEI) about approved prescription drugs by medical product manufacturers, packers, distributers, and their representatives (firms) to payors, formulary committees, or other similar entities with knowledge and expertise in the area of health care economic analysis (collectively referred to as payors). This draft guidance also provides answers to common questions about firms' communications regarding investigational drugs and devices (investigational products) to payors before FDA approval or clearance of such products. The Agency is issuing this draft guidance to explain FDA's current thinking on frequently asked questions regarding such communications in order to provide clarity for firms and payors.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 19, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1307 for ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg.66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Hu Cunningham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3203, Silver Spring, MD 20993–0002, 301–

796–1200; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Paul Gadiock, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5448, Silver Spring, MD 20993–0002, 301–796–5736; or Kristin Davis, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–796–0418.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.'' This draft guidance provides answers to common questions regarding firms' communications of HCEI about their approved prescription drugs to payors. This draft guidance also addresses common questions relating to firms' dissemination of information about investigational products to payors before FDA approval or clearance of such products. For purposes of this draft guidance, the term ''payors'' collectively refers to payors, formulary committees, or other similar entities with knowledge and expertise in the area of health care economic analysis that are responsible for making drug selection, formulary management, and/or coverage and reimbursement decisions on a population basis regarding drugs and/or devices for health care organizations, which may include entities such as integrated health care delivery networks, hospitals, and hospital systems.

FDA is aware that payors seek a range of information on effectiveness, safety, and cost-effectiveness of approved drugs, including information from firms, to help support their drug selection, formulary management, and/or coverage and reimbursement decisions on a population basis. This information may differ from and may be in addition to the information FDA reviews in order to make drug approval decisions. Because coverage and reimbursement decisions by payors impact a large number of patients, FDA believes it is essential that HCEI provided by firms to payors about their approved drugs be truthful and non-misleading.

With respect to HCEI regarding approved drugs, section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)), as amended by section 114 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) and section 3037 of the 21st Century Cures Act (Pub. L. 114–255), includes a provision regarding communication of HCEI about such drugs to payors. Section 502(a) indicates that HCEI provided to payors carrying out their responsibilities for the selection of drugs for coverage or reimbursement shall not be considered to be false or misleading if the HCEI relates to an FDA-approved indication for the drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the FDA-approved labeling for the drug. Section III.A of this draft guidance provides FDA's current thinking on key concepts in section 502(a) and recommendations for how firms can communicate HCEI about approved drugs to payors in accordance with this section to help ensure that payors have information needed to make informed drug selection, formulary management, and/or coverage and reimbursement decisions and to help ensure that the information is not false or misleading. Section III.A also discusses how FDA's requirements for submission of promotional materials apply to HCEI about approved drugs disseminated by firms to payors. If a firm disseminates HCEI about an approved drug in accordance with this draft guidance, when finalized, FDA does not intend to consider such information false or misleading. In addition, FDA does not intend to use HCEI about approved drugs disseminated consistent with this draft guidance, when finalized, as providing evidence of a new intended use.

FDA also recognizes that due in part to their need, in some situations, to plan for and make coverage and reimbursement decisions far in advance of the effective date of such decisions, payors are also interested in receiving information from drug and device firms about medical products that are not yet approved or cleared by FDA for any use (referred to in this draft guidance as investigational products). Section III.B discusses FDA's thinking with respect to communication by firms to payors of information about investigational products. As with HCEI about approved prescription drugs, it is essential that information provided by firms about their investigational products be truthful and non-misleading. Therefore, section III.B also lays out a series of recommendations to help achieve these goals.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled ''Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling—Questions and Answers.'' The guidance provides information for medical product firms about how FDA evaluates their medical product communications, including their promotional materials, that present information that is not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling for the product.

In addition, FDA is announcing in this issue of the **Federal Register** that it is reopening the comment period for the notice of public hearing that appeared in the **Federal Register** of September 1, 2016, concerning manufacturer communications regarding unapproved uses of approved or cleared medical products. The comment period will be reopened for 90 days, until *January 19, 2017.* As announced in the notice of public hearing, FDA is engaged in a comprehensive review of its regulations and policies governing communications by firms about unapproved uses of approved or cleared medical products, and the comments it receives will inform FDA's policy development in this area.

FDA will consider the feedback it receives in all three of these dockets as the Agency continues to review its policies on firm communications about medical products, and interested persons may wish to review the documents FDA has issued in all three dockets before submitting comments to any of the relevant dockets.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the current thinking of FDA on certain commonly asked questions regarding firms' communications with payors. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Drug Manufacturer Communications of Health Care Economic Information to Payors Under FD&C Act Section 502(a); Drug and Device Manufacturer Communications With Payors Regarding Investigational Products.

Description of Respondents: For information that should be included when HCEI is disseminated to payors, respondents to this collection of information are firms that manufacture prescription human drug products, including biological products; for information that should be included with communications with payors about investigational products, respondents to this collection of information are firms that manufacture prescription human drug products, including biological products, and medical devices.

Burden Estimate: This draft guidance includes recommendations regarding information that 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). Specifically, FDA recommends that various aspects of study design and methodology of an economic analysis (*i.e.,* type of analysis, modeling technique, patient population, perspective/viewpoint, treatment comparator, time horizon, outcome measures, cost estimates, and assumptions); factors that limit generalizability of an economic analysis; limitations to an economic analysis; and sensitivity analyses, if applicable, be included in HCEI materials disseminated to payors to allow for informed decision-making and to help ensure that the HCEI is not false or misleading.

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), 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 such selective inclusion of 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), must disclose any additional risk information related to assumptions that vary from the approved labeling. Finally, HCEI materials should disclose potential financial or affiliation biases to the extent reasonably known by firms at the time of dissemination.

If firms choose to make communications to payors about investigational products, FDA recommends that firms include a clear statement with their communications that the product is under investigation and that the safety or effectiveness of the product has not been established. In addition, FDA recommends providing information related to the stage of product development (*e.g.,* the phase of clinical trial in which a product is being studied and how it relates to the overall product development plan). Moreover, FDA recommends that firms provide followup information to payors if previously communicated information becomes outdated as a result of significant changes or as a result of new information regarding the product or its review status.

Based on the post-marketing submissions of promotional materials using Form FDA 2253 received in calendar year (CY) 2015 for prescription drugs, FDA estimates that approximately 400 firms will disseminate 4,000 distinct HCEI materials annually. FDA estimates that it will take firms approximately 20 hours to compile and draft the information that this draft guidance recommends should be included if they choose to disseminate HCEI materials to payors.

Based on the number of prescription drugs and devices approved/cleared in CY 2015, FDA estimates that approximately 520 firms will prepare 1,040 distinct communications of information to payors about their investigational products annually. FDA estimates that it will take firms approximately 0.5 hours to compile and draft the information that this draft guidance recommends should be provided with communications to payors about investigational products. In addition, FDA estimates that approximately half of the firms will spend approximately 2 hours to compile and provide 520 distinct communications of followup information regarding previously communicated information to payors about their investigational products annually.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of information	Number of respondents	Number 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 prescription drugs under section 502(a).	400	10	4,000	20	80,000
Recommended information to be included when firms choose to disseminate pre-approval communications about investigational drugs or devices to payors.	520	2	1,040	0.5 (30 minutes)	520

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of information	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Follow up information to payors regarding previously communicated information about investigational drugs and devices.	260	2	520	2	1,040
Total					81,560

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

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 314.81(b)(3)(i) (Form FDA 2253) have been approved under OMB control number 0910–0001.

III. Other Issues for Consideration

Although section 502(a) is specific to approved drugs and section III.A of this draft guidance addresses firms' communications of HCEI to payors only about approved drugs, FDA is interested in whether similar principles to those outlined in that section should apply to firms' communications of HCEI to payors about approved/cleared devices or whether different principles should be considered. FDA is specifically interested in identifying principles that, if applied to communications of HCEI about approved/cleared devices, could help ensure that such information is truthful and non-misleading and aids payors in making informed selection and/or coverage and reimbursement decisions about these products. FDA is interested in comments from interested parties on any of the topics addressed in this draft guidance and specifically requests comments from interested parties on the extent to which the principles provided in section III.A could be applicable to communications of HCEI about approved/cleared devices. To the extent that interested parties believe that different considerations should apply to medical devices or that guidance is needed on additional issues with respect to medical device firms' communications of HCEI about approved/cleared medical devices to payors, FDA is interested in input on those topics as well.

FDA is also seeking comments from interested parties regarding communications of HCEI about animal drugs. Although FDA recognizes that the audience for HCEI about animal drugs may be different from that identified in section III.A as a result of differences in how payment decisions are made for animal drugs, FDA is interested in learning the extent to which the principles provided in section III.A could be applicable to communications of HCEI about animal drugs with appropriate audiences for such information. To the extent that commenters believe that different considerations should apply to animal drugs or that guidance is needed on additional issues with respect to animal drug firms' communications of HCEI about approved new animal drugs to appropriate audiences, FDA is interested in input on those topics as well.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* or *https://www.regulations.gov.*

Dated: January 6, 2017.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0595]

Advice About Eating Fish, From the Environmental Protection Agency and Food and Drug Administration; Revised Fish Advice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: In June 2014, the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) (the Agencies) jointly released a draft update to a March 2004 document entitled ''What You Need to Know About Mercury in Fish and Shellfish.'' FDA and EPA are now announcing revised fish advice that contains advice and supplemental questions and answers for those who want to understand the advice in greater detail.

FOR FURTHER INFORMATION CONTACT: *FDA:* William R. Jones, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1422, *William.Jones@fda.hhs.gov; EPA:* Lisa Larimer, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., MS 4305T, Washington, DC 20460, 202–566–1017, *Larimer.Lisa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2014 (79 FR 33559), FDA, in coordination with EPA, announced the availability of the draft updated fish advice, entitled ''Fish: What Pregnant Women and Parents Should Know'' (the notice), and made the draft updated advice available for public comment. The draft fish advice was intended to update advice previously published by EPA and FDA in March 2004 (Ref. 1), to make it consistent with the 2010 Dietary Guidelines for Americans and to modify the wording and organization of the 2004 advice to enhance the likelihood that it would be followed by the target audience. The 2004 advice on fish consumption itself was preceded by earlier recommendations published by FDA in September 1994 and revised in May 1995 (*http://www.fda.gov/ohrms/dockets/ac/02/briefing/3872_advisory%207.pdf*), followed by separate, but simultaneously issued, FDA and EPA fish consumption advice in 2001. FDA's 2001 advice addressed commercial fish; EPA's 2001 advice addressed locally caught fish. The 2014 notice announcing the availability of the draft updated fish advice stated that the comment period would be open until 30 days after the last transcript became available from either the FDA Risk