



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2016-N-1149]

Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a 2-day public hearing to obtain input on issues related to communications by manufacturers, packers, and distributors, including their representatives (collectively “firms”), regarding FDA-regulated drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs (collectively, “medical products”). FDA is engaged in a comprehensive review of its regulations and policies governing firms’ communications about unapproved uses of approved/cleared medical products, and the input from this meeting will inform FDA’s policy development in this area. FDA is seeking input on a number of specific questions, but is interested in any other pertinent information participants would like to share.

DATES: The public hearing will be held on November 9 and 10, 2016, from 9 a.m. to 5 p.m.

The meeting may be extended or end early depending on the level of public participation.

Persons seeking to attend or present at the public hearing must register by October 19, 2016.

Electronic or written comments will be accepted after the public hearing until January 9, 2017.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave, Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-N-1149 for “Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Request for Comments.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://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 <http://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 <http://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.

A link to the live Webcast of this public hearing will be available at <http://www.fda.gov/CommunicationsPublicMeeting> on the day of the public hearing. A video record of the public hearing will be available at <http://www.fda.gov/CommunicationsPublicMeeting> following the meeting. A video record of the public hearing will be available at the same Web site address for 1 year.

FOR FURTHER INFORMATION CONTACT: Kristin Davis, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4252, Silver Spring, MD 20993, 301-796-0418, email: CommunicationsPublicMeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is responsible for regulating medical products (i.e., drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Public Health Service Act (PHS Act) as well as all relevant implementing regulations (collectively, “FDA Authorities”) to promote and protect the public health by helping to ensure that these products are safe and effective for their intended uses. As we announced in 2014, FDA is currently engaged in a comprehensive review of the regulatory framework related to firms’ communications about unapproved uses of approved/cleared medical products¹--medical products that may be legally introduced into interstate commerce for at least one other intended use.² The purpose of this review is to help ensure that our implementation of the FDA Authorities (including promulgating and amending regulations, issuing guidance, developing policies, and taking enforcement action) best protects and promotes the public health in view of ongoing developments in science and technology, medicine, health care delivery, and constitutional law.

Under the FDA Authorities, in general, firms are required to submit data and other information to FDA for premarket review demonstrating a medical product is safe and effective for each of its intended uses before they introduce the product into interstate commerce for those intended uses. During FDA premarket review of medical products, the Agency also generally reviews proposed labeling for the intended use(s) of the product to ensure that the labeling provides adequate information for the safe and effective use of the product. The FDA

¹ In this document, the term “unapproved use” encompasses additional intended uses of approved drugs and approved/cleared devices, including devices that are currently marketed pursuant to a 510(k) clearance or exemption.

² See FDA response letter, Docket Nos. FDA-2011-P-0512 and FDA-2013-P-1079 (June 6, 2014), available at <http://www.regulations.gov>.

Authorities also prohibit firms from marketing medical products with false or misleading labeling and similarly restrict certain medical product advertising.

The premarket review and labeling and advertising provisions of the FDA Authorities address critical public health objectives. The current regulatory framework was developed in response to public health tragedies, particularly those that occurred when firms could distribute drugs and devices without independent, premarket review of scientific evidence of the products' safety and efficacy.³ Medical product firms are required to develop high-quality data to demonstrate that medical products are safe and effective for their intended uses before marketing of the products for those uses. This requirement helps ensure that the use of medical products is based on sound science, not mere anecdotal experience or misleading promotional tactics, and helps prevent direct and indirect patient harm from products and uses that are unsafe and/or ineffective. When using a medical product for its FDA approved/cleared intended use, health care professionals and patients and their caregivers can be assured that the decision to use the product is supported by robust premarket review of scientific data and other appropriate scientific evidence by an independent scientific agency and that the benefits and risks of the use are described in the product's FDA-approved or required labeling. These important assurances are absent for unapproved uses. The premarket review requirements also reflect Congress's

³ The Federal Food, Drug, and Cosmetic Act of 1938, which introduced the requirement that firms demonstrate a drug product to be safe before being marketed, followed the deaths of approximately 100 people, mostly children, from ingesting "Elixir Sulfanilamide," in which the lethal substance diethylene glycol was used as a solvent. Prior to 1938, there were no premarket requirements that mandated that the firm test its product's safety. The passage of the 1962 drug amendments was precipitated in part by the distribution of thalidomide, a sedative that caused birth defects when taken by pregnant women. See Wallace F. Janssen, Outline of the History of U.S. Drug Regulation and Labeling, 36 Food Drug-Cosm. L.J. 420 (1981). Significant problems with medical devices likewise preceded the Medical Device Amendments of 1976, including significant defects in cardiac pacemakers that led to 34 voluntary recalls involving 23,000 units, and serious side effects following implantation of intraocular lenses, including serious impairment of vision and the need to remove the eyes of some patients (H.R. Rep. No. 94-853, at 8 (1976)). See also Henry A. Waxman, A History of Adverse Drug Experiences: Congress Had Ample Evidence to Support Restrictions on the Promotion of Prescription Drugs, 58 Food & Drug L.J. 299 (2003); see also Kate Greenwood, The Ban on "Off-Label" Pharmaceutical Promotion: Constitutionally Permissible Prophylaxis Against False and Misleading Commercial Speech?, 37 Am. J. L. and Med. 278, 291-92 (2011) (describing the history of misleading firm claims in promoting unapproved uses).

determination that exclusive reliance on postmarket remedies, such as enforcement actions for false or misleading labeling, is unacceptable as a public health strategy because it does not prevent harm and injury to patients.

Congress also determined that safety and effectiveness must be evaluated for each intended use of a medical product to prevent the harm that occurs when patients are prescribed or use ineffective treatments and to ensure that the benefits of an intended use outweigh its risks. Under the FDA Authorities, FDA evaluates whether a medical product is safe for a particular use by comparing the expected therapeutic benefits against the risk associated with that use. The weighing of benefit and risk for each intended use is necessary as a matter of science to protect the public health: A product considered “safe and effective” for one disease or condition or patient population cannot automatically be considered “safe and effective” for another disease or condition or patient population. For example, a drug with severe adverse effects may be considered safe and effective for treating metastatic lung cancer, but be unlikely to have a positive benefit-risk balance for treating high blood pressure. Similarly, a non-absorbable suture cleared or approved for wound closure on the skin’s surface might raise significant new safety and effectiveness concerns if used internally.

Notwithstanding the importance of the FDA Authorities in protecting public health, health care professionals are generally permitted to prescribe or use approved/cleared medical products for unapproved uses when they judge that the unapproved use is medically appropriate for their individual patients,⁴ and relevant, truthful, and non-misleading scientific or medical information regarding unapproved uses of approved medical products may help health care

⁴ FDA generally does not seek to interfere with the exercise of the professional judgment of health care providers in prescribing, for unapproved uses for individual patients, most legally marketed medical products. This longstanding position has been codified with respect to devices. See 21 U.S.C. 396. While FDA generally recognizes the professional judgment of veterinarians, certain unapproved uses of drugs in animals are not permitted and result in the drug being deemed unsafe under section 512 of the FD&C Act. See section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5)) and 21 CFR part 530.

professionals make better individual patient decisions. For example, health care professionals may consider prescribing or using approved/cleared medical products for unapproved uses in circumstances where a patient has a disease for which there is no approved treatment or has exhausted all approved treatments. In such a situation, relevant, truthful, and non-misleading scientific or medical information about an unapproved use may help a health care professional to make treatment decisions in the absence of scientific data or information that is capable of satisfying FDA's premarket review requirements.

Health care professionals already can access considerable scientific information about unapproved uses, for example, through public sources such as scientific journals, clinical practice guidelines, and compendia or by requesting that information from firms.⁵ FDA is interested in comment on the extent to which additional communications from firms about unapproved uses can provide access to information that is relevant, scientifically sound, responsibly presented, and provides as full an understanding as possible about the limitations of the available evidence, as well as comment on the extent to which health care professionals currently face impediments to accessing such information, whether from firms or from other sources. FDA is interested in comment and information addressing whether and in what ways firms' communications of unapproved use information are distinct and perhaps provide unique benefits compared to other sources.

⁵ See "Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices--Draft Guidance" (December 2011), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf>. FDA has also issued guidance documents to describe some of the circumstances when it would not consider a manufacturer's distribution of reprints, clinical practice guidelines, or reference texts regarding unapproved uses of approved drugs to be evidence of intended use and/or false or misleading. See "Revised Draft Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses--Recommended Practices" (February 2014), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf> ("Revised Good Reprint Practices Draft Guidance"); and "Guidance for Industry: Good Reprint Practices for Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices" (January 2009), available at <http://www.fda.gov/oc/op/goodreprint.html> ("Good Reprint Practices Guidance").

Not all communications of information about unapproved uses help support public health. For example, communications that emphasize a medical product's claimed benefits, while minimizing the limitations of the supporting evidence, or minimizing the product's known or potential adverse effects, may inappropriately influence prescribing or use decisions in a manner that is not in a patient's best interest. FDA is interested in comment on both the pros and cons for public health associated with firms' communications of unapproved use information and the kinds of limitations or requirements that would be appropriate to protect patients from harm. We are also interested in any supporting data related to these issues. In addition, allowing additional communications about unapproved uses could have other indirect consequences on public health, which are important to understand and anticipate. For example, FDA is interested in information to better understand how increased communications about unapproved uses would impact incentives to conduct biomedical research submitted for FDA review and subjects' willingness to participate in such research.

The Agency is aware of technological and business changes that are increasingly affecting medical decision making and prescribing. There are a growing number of entities in the health care system with a stake in evaluating evidence to assess the rational and systematic use of medical products. As medical providers have increasingly been consolidated into integrated systems, the use of system measurements of quality and measurements of the appropriate use of medical products has increased, and insurance carriers, health care systems, and similar entities may restrict coverage for medical products based on assessments of value and employ performance measures to monitor appropriate use and outcomes. FDA is interested in understanding whether and how these changes may be able to provide an impetus for the development of additional high-quality data to address the balance of benefits and risks of each

use of a medical product and, if so, in what way they would affect incentives for submission of this data to the Agency for marketing authorization.

II. Purpose and Scope of the Public Hearing

The purpose of this public hearing is to obtain comments on FDA's regulation of firms' communications about medical products, with a particular focus on firms' communications about unapproved uses of their approved/cleared medical products. FDA is seeking feedback from a broad group of stakeholders, including, but not limited to, health care professionals and professional societies, patients and their caregivers, patient advocates, representatives from regulated industry, health care organizations, payors and insurers, academic institutions, public interest groups, and the general public.

To facilitate stakeholder feedback, FDA sets forth some questions in this section. These questions are not meant to be exhaustive. We encourage interested stakeholders to address these and/or other issues related to firms' communications about their medical products. In all cases, FDA encourages stakeholders to provide the rationale and basis for their comments, including any available data and information, and to explicitly articulate any underlying assumptions. FDA also encourages commenters to explain the basis for any distinctions they would draw as to audience, vehicle of communication, type of medical product, type and source of information, or any other aspect of communication.

1. FDA is interested in input from stakeholders on how increased communications from firms about unapproved uses could impact the public health, and on whether the impact would differ across different categories of medical products. For example,
 - a. What are the benefits for clinical decision making, research, coverage, reimbursement, or other purposes (please specify) if firms communicate to health care professionals, payors,

- researchers, and/or patients more information, including preliminary or inconclusive information, about unapproved uses of approved/cleared medical products? What are the drawbacks and risks? Are there safeguards or requirements that would effectively mitigate any drawbacks or risks?
- b. What information or systems exist to help FDA determine how firms' increased communication of information about unapproved uses of approved/cleared medical products could affect prescribing as well as medical product development and research into new uses of approved/cleared products?
- c. How could firms' increased communication of information about unapproved uses of approved/cleared medical products affect patient incentives to enroll in clinical trials? Related to this, FDA is interested in information on how firms' increased communication of this information could impact their incentives to generate robust data to fully assess the risks and benefits of new uses and to apply for FDA marketing authorization for new uses of approved/cleared products.
- d. Do the answers to the previous questions vary for different categories of medical products (e.g., human drugs and biologics, medical devices, animal drugs) or for different disease areas or patient populations?
2. FDA is aware of changes happening in the health care system that are outside of FDA's role, which may provide an impetus for the development of high-quality data to fully assess the risks and benefits of new uses of medical products.
- a. To what extent do changes occurring in the health care system that give payors and formulary committees more influence on prescribing decisions (including by denying, limiting, or endorsing coverage of unapproved uses of approved medical products)

provide incentives for firms to generate the high-quality data needed to demonstrate safety and effectiveness for new uses?

- b. To what extent do these changes affect (to preserve, enhance, or suppress) incentives for firms to seek FDA approval/clearance of new uses?
3. FDA recognizes that information about medical products, including information about unapproved uses of approved/cleared medical products, is now broadly available from a wide variety of sources (e.g., academic and governmental organizations, scientific journals, professional societies, compendia) in both traditional and new communication vehicles and platforms, particularly electronic communication platforms (e.g., the Internet). What is the impact of the increasing availability of this information on firms' incentives to communicate information about unapproved uses of approved/cleared products? FDA is also interested in input on other factors that firms may consider when making decisions about providing information about unapproved uses of their approved/cleared medical product, including financial considerations.
 4. Given the importance of the scientific integrity of the information that may be relied on in making decisions about the use of medical treatments, FDA is interested in input from stakeholders on the standards that should apply to unapproved use communications to minimize the potential of these communications to be misleading or otherwise cause harm.
For example:
 - a. Given the wide range of quality of information potentially available to firms on unapproved uses of their approved/cleared medical products, what processes do firms use to evaluate whether such information is scientifically appropriate to communicate to health care professionals and other entities?

- b. What criteria should the Agency consider in determining whether a study or analysis that is the basis of a firm's communication is scientifically appropriate to support the presentations or conclusions in the communication?
 - c. What do health care professionals generally understand about the quality and utility of different kinds or levels of scientific evidence related to unapproved uses? Can the same information be misleading to some audiences of health professionals and not others?
 - d. What information is most important to health care professionals and other entities in allowing them to judge the validity and utility of firms' communications about unapproved uses, including the level of uncertainty of the evidence, and why? Does the answer to this question differ depending on the recipient's purpose--e.g., making treatment decisions for an individual patient, informing the direction of further research, making formulary or institutional supply chain contracting decisions, or making coverage determinations?
5. FDA is interested in input from stakeholders on factors that the Agency should consider in evaluating whether firms' communications about unapproved uses of approved/cleared medical products are truthful and non-misleading, including what information firms should disclose in these communications to help ensure audiences are not misled, and on general considerations related to the audience for these communications and on communication vehicles and techniques. For example:
- a. What information should firms communicate to make audiences aware that the medical product is unapproved for the use discussed and to otherwise distinguish between the approved/cleared use(s) of the medical product and the unapproved use? How could the means of communication affect a recipient's ability to distinguish between unapproved

and approved/cleared uses or otherwise impede the disclosure of necessary contextual information?

- b. What factors are most relevant to determining whether a firm's communication about a medical product concerns an unapproved use? How do firms evaluate whether or not their communications concern unapproved uses and whether the messages communicated are accurate and non-misleading?
- c. What other information should firms disclose in these communications to help ensure audiences are not misled (e.g., about the risks of the product, the nature and weight of the evidence supporting the unapproved use, the regulatory history relating to the unapproved use, the financial involvement of firms in the research described, etc.)?
- d. How can disclosures in firms' unapproved use communications be made most effective in conveying material information while minimizing chances of confusion or inattention? How effective are disclosures in ensuring that limitations concerning data about unapproved uses are adequately communicated and comprehended? For example, how could the content and format of disclosures be developed to optimize the usefulness of this information for audiences? FDA is interested in empirical evidence to assess whether health care professionals or other entities follow or disregard different types or formats of disclosures or disclaimers.
- e. To what extent is it appropriate for firms to communicate information about unapproved uses of their approved/cleared medical products to patient and consumer audiences? What disclosures and additional information would be needed to help ensure that a communication to lay audiences is truthful and non-misleading, given consumers' lack of medical training and expertise in critically evaluating this type of information?

6. Another important consideration in the changing health care environment is transparency, including the growing expectation that data from human studies will be made available for public review. If a firm bases a communication on data that is not publicly available, should information be provided publicly to ensure that the quality and integrity of the supportive scientific information can be adequately evaluated before any prescribing or use decision? If so, how should transparency of this information be monitored?
7. FDA is interested in public input on how the Agency should monitor firms' communications about unapproved uses of their medical products, and what actions FDA should take with respect to firms' communications that are determined to be false or misleading or that otherwise raise public health issues. For example, what kinds of surveillance and monitoring could be undertaken to measure and assess the public health impacts of unapproved use communications and by whom?
8. As discussed previously, the Agency is evaluating its regulations and policies governing firms' communications about unapproved uses of approved/cleared medical products and considering whether revisions are appropriate in order to provide greater legal certainty and clarity to regulated entities. As an initial step, in the Federal Register of September 25, 2015 (80 FR 57756), FDA issued a notice of proposed rulemaking that proposed changes to existing regulations at 21 CFR 201.128 and 801.4 to provide clarity for drug and device firms regarding FDA's interpretation and application of its existing intended use regulations.
 - a. What additional changes, if any, should FDA consider in its regulations related to firms' communications about medical products, such as the regulations related to what is false or misleading, adequate directions for use, the definition of labeling, or other relevant provisions?

- b. With respect to proposed alternatives to the current regulations, as well as other proposed alternatives suggested in litigation briefs and journal articles, what are the advantages and disadvantages of these approaches as they relate to the public health objectives that the FDA Authorities are designed to advance?

III. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance is free and early registration is recommended.

Individuals who wish to attend must register on or before October 19, 2016, at <http://www.fda.gov/CommunicationsPublicMeeting> and provide complete contact information, including name, title, affiliation, email, and phone number. Those without Internet access may register by contacting Kristin Davis at 301-796-0418. FDA may allow onsite registration if space is available. If registration reaches maximum capacity, FDA will post a notice closing registration at <http://www.fda.gov/CommunicationsPublicMeeting>.

Individuals who wish to present at the public hearing must register as noted at <http://www.fda.gov/CommunicationsPublicMeeting> and identify the questions (see section II) they wish to address in their presentation to help FDA organize the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted for each oral presentation and the approximate time that each oral presentation is scheduled to begin. FDA will notify registered presenters of their scheduled times and make available an agenda at <http://www.fda.gov/CommunicationsPublicMeeting> on or before November 2, 2016. Once FDA

notifies registered presenters of their scheduled times, presenters must submit an electronic copy of their presentation to CommunicationsPublicMeeting@fda.hhs.gov by October 26, 2016.

If you need special accommodations because of a disability, please send an email to CommunicationsPublicMeeting@fda.hhs.gov at least 7 days before the meeting.

A link to the live Webcast of this public hearing will be available at <http://www.fda.gov/CommunicationsPublicMeeting> on the day of the public hearing. A video record of the public hearing will be available at <http://www.fda.gov/CommunicationsPublicMeeting> following the meeting. A video record of the public hearing will be available at the same Web site address for 1 year.

IV. Notice of Public Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner and the relevant centers/offices.

Under § 15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (§ 15.30(e)). Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section V). To the extent that the

conditions for the hearing as described in this document conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>.

Dated: August 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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