**Appendices to Recordkeeping—Commission Voting Summary and Chairman's Statement**

**Appendix 1—Commission Voting Summary**

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

**Appendix 2—Statement of Chairman Timothy G. Massad**

I have said many times that it is important for the CFTC to ensure its rules are up-to-date in light of technological changes, as outdated rules can create unnecessary burdens. That is why I'm pleased we are unanimously issuing this proposed rulemaking, which is in keeping with that goal.

Today's proposal will modernize recordkeeping and storage obligations set forth in CFTC rules, and make them technology neutral. By doing so, it will reduce costs for businesses and improve the quality of record preservation and production. Among other things, the proposal will provide greater flexibility when it comes to how records must be retained and produced. In this age where terabytes of storage easily fit in one's pocket, our rules should not refer to microfiche or require paper records.

Today's proposal is also an example of how the Commission is focusing on issues related to technological change generally in our markets. In this regard, there is much talk today about innovations that may come from financial technology. While it is the role of the private sector to develop innovations, I believe it is our role to ensure that the Commission's rules do not stand in the way of their potential. Today's proposal is a way to do just that.

I thank the CFTC staff for their work on this proposal and my fellow Commissioners for their support.

[FR Doc. 2017–01148 Filed 1–18–17; 8:45 am]

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## 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; Availability of Memorandum; Reopening of the Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Reopening of comment period related to public hearing; availability of memorandum.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for the notification of public hearing, published in the **Federal Register** of September 1, 2016 (81 FR 60299) concerning our comprehensive review of our regulations and policies governing manufacturer communications regarding unapproved uses of approved or cleared medical products. FDA is also announcing that it has added a document to the docket for the public hearing entitled ''Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products'' (Memorandum). The Memorandum provides additional background on the issues FDA is considering as part of its comprehensive review, including a discussion of First Amendment considerations. In addition, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two draft guidance for industry that address manufacturer communications, one entitled ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers,'' and the other entitled ''Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers.'' FDA is reopening the comment period to provide the public an opportunity to review the Memorandum as it relates to the specific questions and issues identified in the notification of public hearing as well as review the two draft guidances and provide additional or new comments.

**DATES:** Submit either electronic or written comments 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–N–1149 for ''Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Requests for Comments.'' 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.

**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.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 1, 2016 (81 FR 60299), FDA published a notification of public hearing on firm communications regarding unapproved uses of approved or cleared medical products. FDA is currently engaged in a comprehensive review of its regulations and policies governing firms' communications about unapproved uses of approved or cleared medical products, and the comments on the notification of public hearing will inform FDA's policy development in this area.

Interested persons were originally given until January 9, 2017, to comment on the topics discussed in the notification of public hearing.

At the public hearing on November 9 and 10, 2016, a number of speakers presented legal views regarding the application of First Amendment principles to firm communications regarding unapproved uses of approved or cleared medical products. Some expressed the view that FDA had not sufficiently discussed the First Amendment in the notification of public hearing. In response to these comments, FDA is now placing the Memorandum in the docket for the public hearing to provide additional background on the issues it is considering as part of its review of its rules and policies relating to firm communications regarding unapproved uses of approved or cleared medical products, including a discussion of First Amendment considerations. In the notification of public hearing, FDA requested comments on a number of specific issues and questions identified throughout the document. The Memorandum is intended to help advance the discussion of these topics, and FDA is seeking input on the information in the Memorandum as it relates to these issues and questions in the notification of public hearing.

Furthermore, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers,'' which provides answers to common questions regarding the communication of health care economic information about approved prescription drugs by medical product firms to payors, formulary committees, or other similar entities. The draft guidance also provides answers to common questions related to firms' communications about investigational drugs and devices (investigational products) to payors before FDA approval or clearance of such products.

Additionally, 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 FDA-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.

FDA is harmonizing the comment periods for the notification of public hearing and the two draft guidances, as all three documents relate to the overarching topic of firm communications regarding medical products, and interested persons may wish to review all the documents before submitting comments to any of the relevant dockets. FDA is requesting comments on both draft guidances by April 19, 2017.

To allow interested parties an opportunity to review the Memorandum and the two draft guidances, FDA is reopening the comment period for the notification of public hearing for an additional 90 days, until April 19, 2017. The Agency believes reopening the comment period for an additional 90 days for the notification of public hearing will allow adequate time for interested persons to submit comments without significantly delaying Agency decision making and policy development on these important issues.

Dated: January 6, 2017.

**Jeremy Sharp,**

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

[FR Doc. 2017–01013 Filed 1–18–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[REG–127203–15]**

**RIN 1545–BN81**

## Transfers of Certain Property by U.S. Persons to Partnerships With Related Foreign Partners

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking by cross-reference to temporary regulation.

**SUMMARY:** In the Rules and Regulations section of this issue of the **Federal Register**, temporary regulations are being issued under sections 197, 704, 721(c), and 6038B of the Internal Revenue Code (Code) that address transfers of appreciated property by U.S. persons to partnerships with foreign partners related to the transferor. The temporary regulations affect U.S. partners in domestic or foreign partnerships. The text of the temporary regulations also serves as the text of these proposed regulations.