4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4361]

Gifts to the Food and Drug Administration: Evaluation and Acceptance; Guidance for the Public and Food and Drug Administration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a guidance for industry entitled "Gifts to FDA: Evaluation and Acceptance." The Secretary of the Department of Health and Human Services (HHS) has the authority to accept conditional or unconditional gifts on behalf of the United States. The Secretary has delegated this gift authority to the Commissioner of Food and Drugs. This guidance provides the process and principles we will use in implementing this authority.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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-2015-D-4361 for "Gifts to FDA: Evaluation and Acceptance: Guidance for the Public and FDA Staff; Availability." 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 guidance to the Office of Policy, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, Bldg. 32, rm. 4238, 10903 New Hampshire Ave., Silver Spring, MD, 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Robert Berlin, Office of Policy, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, Bldg. 32, rm. 4238, 10903 New Hampshire Ave., Silver Spring, MD, 20993, 301-796-8828, robert.berlin@fda.hhs.gov. Alternate contact: Office of Policy, 301-796-4830.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for the public and FDA staff entitled "Gifts to FDA: Evaluation and Acceptance." The Secretary of HHS has the authority to accept conditional or unconditional gifts on behalf of the United States. The Secretary has delegated this gift authority to the Commissioner of Food and Drugs. This guidance provides the process and principles we will use in implementing this authority.

FDA will consider gifts from all sources except the Reagan-Udall Foundation (RUF) on a case-by-case basis using a balancing test, described in the guidance. While any person may offer a gift, there are five reasons we should reject a gift without additional evaluation. We should not accept a gift if: (1) The donor imposes conditions that are illegal, are contrary to public policy, are unreasonable to administer, are contrary to FDA's current policies and procedures, or are contrary to generally accepted public standards; (2) the donor requires us to provide the donor with some privilege, concession, or other present or future benefit in return for the gift; (3) a

debarred entity offers the gift; (4) a different authority or financial mechanism applies; or (5) the total costs associated with acceptance are expected to exceed the cost of purchasing a similar item and the cost of normal care and maintenance.

In the Federal Register of June 29, 2016 (81 FR 42365), FDA announced the availability of a draft guidance entitled "Gifts to FDA: Evaluation and Acceptance: Evaluation and Acceptance." FDA received one comment expressing concern regarding the policy described in the guidance. It appears the commenter may have misunderstood the policy and incorrectly believed that gifts would not be limited, would be unreported, and would be provided to Federal employees themselves. As explained in the guidance, that is not the case. Rather, the recipients of any gifts would be the Agency, gifts are extensively reviewed to ensure receipt would be appropriate, and the Agency intends to publish a summary of received gifts. The Agency has made only minor changes to the guidance to clarify that the evaluation of gifts from RUF will reflect RUF's unique role in support of the Agency and the statutory safeguards in 21 U.S.C. 379dd. In addition, the discussion of restrictions on funds for travel has been clarified to better reflect the scope of statutes and policies governing the use of non-Agency funds for travel.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this matter. 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. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/RegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: December 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-30312 Filed: 12/15/2016 8:45 am; Publication Date: 12/16/2016]