they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their requests to speak by October 28, 2015.

B. Comments

Regardless of whether you attend this meeting, you can submit either electronic comments regarding this public workshop to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document and must be received by December 29, 2015. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

C. Transcripts

Transcripts of the workshop will be available for review at the Division of Dockets Management (see *Comments*) and at *http://www.regulations.gov* approximately 30 days after the workshop. 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: September 3, 2015

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22784 Filed 9–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3056]

Distributor Labeling for New Animal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GIF) #231 entitled ''Distributor Labeling for New Animal Drugs.'' This draft guidance discusses FDA's current thinking with respect to the factors it considers in determining whether to take regulatory action against distributor labeling for a new animal drug that differs from the labeling approved as part of a New Animal Drug Application or Abbreviated New Animal Drug Application (NADA/ANADA) in ways other than those permitted by regulation.

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 November 9, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dorothy McAdams, Center for Veterinary Medicine, Division of Surveillance (HFV–210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5763, email: *dorothy.mcadams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #231 entitled ''Distributor Labeling for New Animal Drugs.'' ''Distributor labeling'' refers to the labeling of an approved new animal drug marketed by a distributor who distributes the product under its own label or proprietary name. Unlike the approved labeling, which the Center for Veterinary Medicine reviews as part of a NADA/ANADA approval process to ensure the safe and effective use of the drug and compliance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and its implementing regulations, distributor labeling does not ordinarily go through a premarket approval process.

FDA regulations (21 CFR 514.80) require that distributor labeling be identical to the labeling approved in the NADA/ANADA, except for a different and suitable proprietary name and the name and address of the distributor preceded by an appropriate qualifying phrase. These requirements are meant to ensure that distributor labeling complies with the requirements of the FD&C Act and its implementing regulations and to prevent distributor label products from reaching the market with labeling that compromises the safe and effective use of the new animal drug.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on distributor labeling for new animal drugs. 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 514.80 have been approved under OMB control number 0910–0284.

IV. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of

comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: September 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22772 Filed 9–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3106]

Animal Food; Export Certificates; Food and Drug Administration Food Safety Modernization Act of 2011; Certification Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fees we will assess for issuing export certificates for animal food. The FDA Food Safety Modernization Act (FSMA) of 2011 authorizes us to charge fees to cover our costs associated with issuing export certificates for regulated food including animal food. This notice provides the fee schedule for issuing these certificates and the basis for the fees. We have not previously collected fees to issue export certificates for animal food.

DATES: The fees described in this document for export certificates for animal food will be effective October 1, 2015.

FOR FURTHER INFORMATION CONTACT: Joanne Kla, Office of Surveillance and Compliance, Center for Veterinary Medicine (HFV–235), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5605, *CVMExportCertification@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In April 1996, a law entitled the ''FDA Export Reform and Enhancement Act of 1996'' (Pub. L. 104–134, amended by Pub. L. 104–180) amended sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FD&C Act provides that persons exporting certain FDA regulated products may request FDA to certify that the products meet the requirements of section 801(e)(1), section 802, or other applicable requirements of the FD&C Act. Section 801(e)(4) of the FD&C Act also requires FDA to issue certification within 20 days of receipt of the request and authorizes us to charge up to $175 for each certification issued within 20 days. In January 2011, section 801(e)(4)(A) of the FD&C Act was amended by FSMA (Pub. L. 111–353) to provide authorization for export certification fees for regulated food, including animal food (referred to as animal feed in section 107(b) of FSMA). Section 801(e)(4) of the FD&C Act authorizes FDA to issue export certificates for regulated food, drugs, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are legally exported under section 801(e) or 802 of the FD&C Act. The focus of this notice is on export certificates issued by the Center for Veterinary Medicine (CVM) for animal food.

II. Fees To Be Assessed for Export Certificates

CVM estimates the costs of the export certification program for animal food to be approximately $548,000 per year for payroll and operating expenses. There are four cost categories for preparing and issuing export certificates in general. They are: (1) Direct personnel for research, review, tracking, writing, and assembly; (2) purchase of equipment and supplies used for tracking, processing, printing, and packaging. Recovery of the cost of the equipment is calculated over its useful life; (3) billing and collection of fees; and (4) overhead and administrative support. In fiscal year (FY) 2014 CVM issued approximately 933 animal food export certificates. Because CVM has not been charging fees for issuing export certificates for animal food, the program has been covered by appropriated funds.

As mentioned previously in this document, FDA may charge up to $175 for each certificate. Certificates for some classes of products, including animal food, cost the Agency more than $175 to prepare. Subsequent certificates issued for the same product(s) in response to the same request generally cost FDA less than $175 to prepare. The fee for all subsequent certificates for the same product(s) issued in response to the same request reflects reduced FDA costs for preparing those certificates.

The following fees will be assessed starting October 1, 2015, for animal food export certificates:

TABLE 1—CVM FEES FOR FIRST, SECOND, AND SUBSEQUENT EXPORT CERTIFICATES

Type of certificate	Fee (dollars)
First certificate	175
Second certificate for the same product(s) issued in response to the same request	155
Subsequent certificates for the same product(s) issued in response to the same request	70

The fee for issuing the first export certificate for animal food will be at the maximum allowable amount and consistent with the export certification fees assessed since FY 1997 by other FDA Centers that provide export certification for drugs and devices. The fees for issuing subsequent certificates continue to differ among the Centers, based on varying costs.

Dated: September 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22795 Filed 9–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0481]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''New Animal Drugs for Investigational Use'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food