Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–4500]

Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs With a New World Screwworm-Related Indication; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry (GFI) #299 entitled ''Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs With a New World Screwworm-Related Indication.'' This guidance is intended to inform new animal drug sponsors that dual labeling of a new animal drug product may include an intended use that is fully approved under section 512(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and an intended use that is conditionally approved under section 571 of the FD&C Act where the claim to be added to the existing product labeling is intended to treat or prevent New World screwworm myiasis.

DATES: The announcement of the guidance is published in the **Federal Register** on October 16, 2025.

ADDRESSES: You may submit either electronic or written/paper comments on Agency guidances at any time 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2025–D–4500 for ''Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs With a New World Screwworm-Related Indication.'' 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 Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, 5100 Campus Drive, College Park, MD 20740–3840. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *ASKCVM@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of guidance for industry #299 entitled ''Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs With a New World Screwworm-Related Indication.'' We are issuing this

guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without initially seeking prior public comment because we have determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2)). We made this determination in light of the significant potential for a public health emergency associated with New World Screwworm, *Cochliomyia hominivorax,* (NWS).

NWS is a parasitic fly that lays eggs in and on open wounds and mucous membranes of warm-blooded animals. NWS can infest livestock, pets, wildlife, occasionally birds, and in rare cases, people. Although eradicated from North America and Central America decades ago, NWS has progressed north since 2022 and is approaching the U.S. border with Mexico. This parasite poses an emerging threat to livestock and food security, with potential impacts on both national security and animal health. In order to respond effectively and efficiently to this threat, FDA must act expeditiously to review and, where appropriate, approve or authorize animal drugs for NWS myiasis.[1] Such approvals may include conditional approvals under section 571 of the FD&C Act for new indications for products that are currently approved for a different indication(s) under section 512 of the FD&C Act.

Section 571(f)(2) of the FD&C Act permits the agency, through regulation or guidance, to determine under what conditions an intended use that is the subject of a conditional approval may be included in the same product label with any intended use approved under section 512 of the FD&C Act, *i.e.,* a full approval. The guidance document refers to this practice as ''dual labeling.'' While FDA intends to issue guidance in the future to more broadly address conditions under which it would consider dual labeling appropriate, FDA is issuing this guidance concerning products with indications for NWS at this time due to the particular need to act quickly and efficiently to address the imminent health threat of NWS.

Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

The guidance represents the current thinking of FDA on ''Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs With a New World Screwworm-Related Indication.'' 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.

[1] We note that this guidance document is relevant to new animal drugs with approved and conditionally approved claims. Emergency Use Authorizations under section 564 of the FD&C Act are outside the scope of this guidance.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in sections 512 and 571 of the FD&C Act (21 U.S.C. 360b) have been approved under 0910–0032. The collections of information in 21 CFR 514.80 have been approved under 0910–0284.

III. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Modification of the National Customs Automation Program Test Regarding Periodic Monthly Statements

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces a change to the U.S. Customs and Border Protection's (CBP) National Customs Automation Program (NCAP) test concerning Periodic Monthly Statements to reflect that test participants must transmit the payment of supplemental duty bills resulting from an underpayment of estimated duties, taxes, and fees electronically via Automated Clearinghouse (ACH). Except to the extent expressly announced or modified by this document, all aspects, rules, terms and conditions announced in previous notices regarding the test remain in effect. For ease of reference, CBP is reproducing the entire test, with changes, in this document.

DATES: The modification announced in this test will become operational on December 15, 2025.

ADDRESSES: Comments concerning this test program may be submitted via email to Ryan Archer at *ACECollections@cbp.dhs.gov* with a subject line identifier reading, ''Periodic Monthly Statements.''

FOR FURTHER INFORMATION CONTACT: For policy-related questions pertaining to ACH payment capabilities, contact Ryan Archer, Cargo Section Chief, Revenue Division at (317) 298–1200, ext. 1098 or at *ACH-CUSTOMS@cbp.dhs.govmailto:.* For policy-related questions pertaining to billing, contact Jessica Vandemark, Financial Risk and Analysis Section Chief, Revenue Division at (317) 614–4811 or at *billinginquiry@cbp.dhs.gov.* For technical questions related to transmissions using the Automated Broker Interface (ABI), contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to the Client Services Division at *gmb.clientrepoutreach@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION: On February 4, 2004, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** that announced a plan to conduct a test concerning Periodic Monthly Statements (hereinafter, referred to as the ''PMS test''). The PMS test allows an importer or an importer's designated broker to deposit estimated duties, taxes, and fees on a monthly basis via Automated Clearinghouse (ACH) payment processes. *See* 69 FR 5362 (February 4, 2004). CBP modified and clarified the PMS test in fourteen (14) subsequent **Federal Register** notices published on: September 8, 2004 (69 FR 54302); February 1, 2005 (70 FR 5199); August 8, 2005 (70 FR 45736); September 22, 2005 (70 FR 55623); January 20, 2006 (71 FR 3315); June 2, 2006 (71 FR 32114); October 17, 2008 (73 FR 61891); December 12, 2016 (81 FR 89482); January 9, 2017 (82 FR 2385); January 17, 2017 (82 FR 4901); June 8, 2017 (82 FR 26699); June 30, 2017 (82 FR 29910); November 1, 2017 (82 FR 50656); and September 5, 2019 (84 FR 46749).

In addition to payment of estimated duties, taxes, and fees on a monthly basis, PMS test participants may also owe supplemental duties resulting from an underpayment of estimated duties, taxes, and fees. Currently, such