

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-1993-D-0285 for "Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis." 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, Food and Drug Administration, 7500 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.

#### FOR FURTHER INFORMATION CONTACT:

Paulette Salmon, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-6556, [pauline.salmon@fda.hhs.gov](mailto:pauline.salmon@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft revised GFI #49 entitled "Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis." This draft guidance replaces final GFI #49, issued in April 1996 entitled "Target Animal Safety And Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products (Lactating and Non-Lactating Cow Products)." This draft guidance provides recommendations and considerations for bovine mastitis drug products with antibacterial activity that are administered by intramammary infusion. However, this guidance may also be applicable to mastitis products administered by other routes or to products using other technologies (including those with non-antibacterial mechanisms of action).

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 "Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis." 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. Paperwork Reduction Act of 1995

While this guidance contains no 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 21 CFR 514 have been approved under OMB control number 0910-0032; 21 CFR 511.1 have been approved under OMB control number 0910-0117.

##### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: November 25, 2024.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Neurodevelopment, Oxidative Stress, and Synaptic Plasticity Fellowship Study Section.

*Date:* December 20, 2024.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Robert C. Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5190, MSC 7846, Bethesda, MD 20892, 301-435-3009, [elliottro@csr.nih.gov](mailto:elliottro@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

*Dated:* November 29, 2024.

**Victoria E. Townsend,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2024-28391 Filed 12-3-24; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

[CBP Dec. 24-17]

#### Notice of Finding That Aluminum Extrusions and Profile Products and Derivatives Produced or Manufactured Wholly or in Part by Kingtom Aluminio S.R.L. With the Use of Convict, Forced or Indentured Labor Are Being, or Are Likely To Be, Imported Into the United States

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

**ACTION:** General notice of forced labor finding.

**SUMMARY:** This document notifies the public that U.S. Customs and Border Protection (CBP), with the approval of the Secretary of Homeland Security, has determined that aluminum extrusions and profile products and derivatives produced or manufactured wholly or in part by Kingtom Aluminio S.R.L. with the use of convict, forced or indentured labor, are being, or are likely to be, imported into the United States.

**DATES:** This Finding applies to any merchandise described in Section II of this Notice that is imported on or after

December 4, 2024. It also applies to any merchandise described in Section II of this Notice that has already been imported and has not been released from CBP custody before December 4, 2024.

#### FOR FURTHER INFORMATION CONTACT:

Brian M. Hoxie, Director, Forced Labor Division, Trade Remedy Law Enforcement Directorate, Office of Trade, (202) 841-3081 or [forcedlabor@cbp.dhs.gov](mailto:forcedlabor@cbp.dhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Pursuant to section 307 of the Tariff Act of 1930, as amended (19 U.S.C. 1307), “[a]ll goods, wares, articles, and merchandise mined, produced or manufactured wholly or in part in any foreign country by convict labor or/and forced labor or/and indentured labor under penal sanctions shall not be entitled to entry at any of the ports of the United States, and the importation thereof is hereby prohibited.” Under this section, “forced labor” includes “all work or service which is exacted from any person under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily” and includes forced or indentured child labor.

U.S. Customs and Border Protection (CBP) regulations promulgated under the authority of 19 U.S.C. 1307 are found at sections 12.42 through 12.45 of title 19 of the Code of Federal Regulations (CFR) (19 CFR 12.42–12.45). Among other things, these regulations allow any person outside of CBP to communicate a belief that a certain “class of merchandise . . . is being, or is likely to be, imported into the United States [in violation of 19 U.S.C. 1307].” 19 CFR 12.42(a), (b). Upon receiving such information, the Commissioner of CBP will initiate an investigation if warranted by the circumstances. 19 CFR 12.42(d). CBP also has the authority to self-initiate an investigation. 19 CFR 12.42(a).

If the Commissioner of CBP finds that the information available “reasonably but not conclusively” demonstrates that such merchandise within the purview of 19 U.S.C. 1307 is being, or is likely to be, imported into the United States, the Commissioner of CBP will order port directors to seize and withhold the merchandise pending further instructions. 19 CFR 12.42(e). After issuance of such a withhold release order, the covered merchandise will be detained by CBP for an admissibility determination and will be excluded unless the importer demonstrates that the merchandise was not made using

labor in violation of 19 U.S.C. 1307. 19 CFR 12.43–12.44. The importer may also export the merchandise. 19 CFR 12.44(a).

These regulations also set forth the procedure for the Commissioner of CBP to issue a Finding when he determines that the merchandise is subject to the provisions of 19 U.S.C. 1307. Pursuant to 19 CFR 12.42(f), if the Commissioner of CBP finds that merchandise within the purview of 19 U.S.C. 1307 is being, or is likely to be, imported into the United States, the Commissioner will, with the approval of the Secretary of Homeland Security, publish a Finding to that effect in the Customs Bulletin and in the **Federal Register**.<sup>1</sup> Under the authority of 19 CFR 12.44(b), CBP may seize and forfeit imported merchandise covered by a Finding.

Through its investigation, CBP has determined that there is sufficient information to support a Finding that Kingtom Aluminio S.R.L. is using convict, forced, or indentured labor in a factory in the Dominican Republic to produce or manufacture in whole or in part aluminum extrusions and profile products and derivatives, and that such products are being, or are likely to be, imported into the United States.

##### II. Finding

###### A. General

Pursuant to 19 U.S.C. 1307 and 19 CFR 12.42(f), it is hereby determined that certain articles described in section II.B. of this Notice, that are produced or manufactured in whole or in part with the use of convict, forced, or indentured labor by Kingtom Aluminio S.R.L., are being, or are likely to be, imported into the United States. Based upon this determination, the port director may seize the covered merchandise for violation of 19 U.S.C. 1307 and commence forfeiture proceedings pursuant to 19 CFR part 162, subpart E, unless the importer establishes by satisfactory evidence that the merchandise was not produced or manufactured in any part with the use of prohibited labor specified in this Finding. 19 CFR 12.42(g).

<sup>1</sup> Although the regulation states that the Secretary of the Treasury must approve the issuance of a Finding, the Secretary of the Treasury delegated this authority to the Secretary of Homeland Security in Treasury Order No. 100-16, 68 FR 28322 (May 23, 2003). Under Delegation Order 7010.3, Section II.A.3, the Secretary of Homeland Security delegated the authority to issue a Finding to the Commissioner of CBP, with the approval of the Secretary of Homeland Security. The Commissioner of CBP, in turn, delegated the authority to make a Finding regarding prohibited goods under 19 U.S.C. 1307 to the Executive Assistant Commissioner, Office of Trade.