''software'', refers to only that portion of ''technology'' or ''software'' which is peculiarly responsible for achieving or exceeding the controlled performance levels, characteristics or functions. Such ''required'' ''technology'' or ''software'' may be shared by different products. For example, assume product ''X'' is controlled if it operates at or above 400 MHz and is not controlled if it operates below 400 MHz. If production technologies ''A'', ''B'', and ''C'' allow production at no more than 399 MHz, then technologies ''A'', ''B'', and ''C'' are not ''required'' to produce the controlled product ''X''. If technologies ''A'', ''B'', ''C'', ''D'', and ''E'' are used together, a manufacturer can produce product ''X'' that operates at or above 400 MHz. In this example, technologies ''D'' and ''E'' are ''required'' to make the controlled product and are themselves controlled under the General Technology Note. (See the General Technology Note.)

Note 1 to the definition of *required*: The references to ''characteristics'' and ''functions'' are not limited to entries on the CCL that use specific technical parameters to describe the scope of what is controlled. The ''characteristics'' and ''functions'' of an item listed are, absent a specific regulatory definition, a standard dictionary's definition of the item. For example, ECCN 9A610.a controls ''military aircraft specially designed for a military use that are not enumerated in USML paragraph VIII(a).'' No performance level is identified in the entry, but the control characteristic of the aircraft is that it is specially designed ''for military use.'' Thus, any technology, regardless of significance, peculiar to making an aircraft ''for military use'' as opposed to, for example, an aircraft controlled under ECCN 9A991.a, would be technical data ''required'' for an aircraft specially designed for military use thus controlled under ECCN 9E610.

Note 2 to the definition of *required*: The ITAR and the EAR often divide within each set of regulations or between each set of regulations:

1. Controls on parts, components, accessories, attachments, and software; and

2. Controls on the end items, systems, equipment, or other items into which those parts, components, accessories, attachments, and software are to be installed or incorporated.

Moreover, with the exception of technical data specifically enumerated on the USML, the jurisdictional status of unclassified technical data or ''technology'' is the same as the jurisdictional status of the defense article or ''item subject to the EAR'' to which it is directly related. Thus, if technology is directly related to the production of a 9A610.x aircraft component that is to be integrated or installed in a USML VIII(a) aircraft, then the technology is controlled under ECCN 9E610, not USML VIII(i).

* * * * *

''*Technology*'' means:

(a) Except as set forth in paragraph (b) of this definition:

(1) Information necessary for the ''development,'' ''production,'' ''use,'' operation, installation, maintenance, repair, overhaul, or refurbishing (or other terms specified in ECCNs on the CCL that control ''technology'') of an item. ''Technology'' may be in any tangible or intangible form, such as written or oral communications, blueprints, drawings, photographs, plans, diagrams, models, formulae, tables, engineering designs and specifications, computer-aided design files, manuals or documentation, electronic media or information gleaned through visual inspection;

Note to paragraph (a)(1) of this definition: The modification of an existing item creates a new item and technology for the modification is technical data for the development of the new item.

(2) [Reserved];

(3) [Reserved];

(4) [Reserved]; or

(5) Information, such as decryption keys, network access codes, or passwords, that would allow access to other ''technology'' in clear text or ''software.''

(b) ''Technology'' does not include:

(1) Non-proprietary general system descriptions;

(2) Information on basic function or purpose of an item; or

(3) Telemetry data as defined in note 2 to Category 9, Product Group E (see Supplement No. 1 to Part 774 of the EAR).

* * * * *

Transfer. A shipment, transmission, or release of items subject to the EAR either within the United States or outside the United States. *For in-country transfer/transfer (in-country),* see § 734.16 of the EAR.

Note to definition of *transfer*: This definition of ''transfer'' does not apply to § 750.10 of the EAR or Supplement No. 8 to part 760 of the EAR. The term ''transfer'' may also be included on licenses issued by BIS. In that regard, the changes that can be made to a BIS license are the non-material changes described in § 750.7(c) of the EAR. Any other change to a BIS license without authorization is a violation of the EAR. See §§ 750.7(c) and 764.2(e) of the EAR.

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Dated: May 18, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–12843 Filed 6–2–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2010–N–0155]

Veterinary Feed Directive Regulation Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Draft revised guidance; availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for industry (GIF) #120 entitled ''Veterinary Feed Directive Regulation Questions and Answers.'' The purpose of this document is to describe the current Veterinary Feed Directive (VFD) requirements for veterinarians, feed manufacturers and other distributors, animal producers, and other parties involved in the distribution or use of medicated feed containing a veterinary feed directive drug (VFD feed). This draft revised guidance reflects changes to the VFD requirements under the VFD final rule.

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 August 3, 2015.

ADDRESSES: Submit written requests for single copies of the 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: Dragan Momcilovic, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6856, *dragan.momcilovic@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft revised GFI #120 entitled ''Veterinary Feed Directive Regulation Questions and Answers.'' The audience for this draft guidance is comprised of veterinarians issuing VFD orders, feed mills manufacturing VFD feeds and other distributors, animal producers who obtain VFD feeds for use in treating their animals, and others. This draft revised guidance reflects changes to the VFD requirements under the VFD final rule published elsewhere in this edition of the **Federal Register**.

In 1996, Congress enacted the Animal Drug Availability Act (ADAA) to facilitate the approval and marketing of new animal drugs and medicated feeds. In passing the ADAA, Congress created a new regulatory category for certain animal drugs used in animal feed called veterinary feed directive (VFD) drugs. VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian. FDA published final regulations implementing the VFD-related provisions of the ADAA in 2000.

Elsewhere in this edition of the **Federal Register**, FDA is publishing a VFD final rule that revises those VFD regulations and introduces clarifying changes to specified definitions. This draft revised guidance includes revisions that are consistent with the requirements in that final rule.

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 Agency's current thinking on this topic. It does not establish any rights for or on any person and does is not binding on FDA or the public. An alternative approach may be used if such approach 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 21 CFR 558.6 have been approved under OMB control number 0910–0363.

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: May 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13394 Filed 6–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–415]

Schedules of Controlled Substances: Removal of [^{123}I]Ioflupane From Schedule II of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes to remove [^{123}I]ioflupane from the schedules of the Controlled Substances Act. This action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after an opportunity for a hearing through formal rulemaking. [^{123}I]Ioflupane is, by definition, a schedule II controlled substance because it is derived from cocaine via ecgonine, both of which are schedule II controlled substances. This action would remove the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle [^{123}I]ioflupane.

DATES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before July 6, 2015. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)'', may file a request for hearing or waiver of participation pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45, 1316.47, 1316.48, or 1316.49, as applicable. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before July 6, 2015.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–415'' on all correspondence, including any attachments.

- *Electronic comments:* The DEA encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a comment *in lieu of* submitting a comment online, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for hearing must be sent to: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion