drugs (*e.g.,* OxyContin) and illicit opioid drugs (*e.g.,* heroin). It is currently the standard treatment for those experiencing overdose and is commonly used by trained medical personnel in emergency departments and on ambulances. Its use among nonmedical personnel has also increased in recent years. The purpose of the public meeting is to explore issues surrounding the uptake of naloxone to treat opioid drug overdose. The meeting agenda will include topics on the clinical, regulatory, and legal implications of making naloxone more widely available. FDA will post the agenda and additional public meeting material approximately 2 days before the workshop at: *http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm.*

II. Transcripts

A transcript will be made available approximately 45 days after the public meeting. It will be accessible at *http://www.regulations.gov* and may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12061 Filed 5–18–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1196]

List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: The Food and Drug Administration (FDA) intends to develop a list of bulk drug substances that may be used by outsourcing facilities registered under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to compound animal drugs, in accordance with FDA's draft guidance for industry #230, ''Compounding Animal Drugs from Bulk Drug Substances.'' You may nominate specific bulk drug substances for this list. This notice describes the information that should be provided to the Agency in support of each nomination.

DATES: To ensure that FDA considers your nominations for the initial version of the bulk drug substances list, submit either electronic or written nominations for the bulk drug substances list by August 17, 2015.

After the comment period is closed, nominations to add or remove bulk drug substances from the list may be submitted to FDA by citizen petition under § 10.30 (21 CFR 10.30).

ADDRESSES: You may submit nominations by any of the following methods.

Electronic Submissions

Submit electronic nominations in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written nominations in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2013–N–1524. All nominations received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting nominations, see the ''Request for Nominations'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or nominations received, go to *http://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.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine, Food and Drug Administration (HFV–210), 7519 Standish Pl., Rockville, MD 20855, 240–402–5745, *neal.bataller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 503A (21 U.S.C. 353a) and 503B (21 U.S.C. 353b) of the FD&C Act do not apply to the compounding of animal drugs. The FD&C Act does not distinguish between compounding animal drugs from bulk drug substances [1] and any other manufacturing or processing of animal drugs. Except with respect to the limited exemption provided by the FD&C Act described in this document, statutory provisions applicable to manufactured animal drugs under the FD&C Act also apply to compounded animal drugs.

Section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5)) provide a limited exemption from certain requirements for use for compounded animal drugs made from already approved animal or human drugs. Such use is considered an extra-label use and the FD&C Act provides that a compounded drug is exempt from the approval requirements and requirements of section 502(f)(1) (21 U.S.C. 352(f)(1)) of the FD&C Act, if it meets the conditions set out in the statute and the extra-label use regulations at 21 CFR part 530.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances'' (GFI #230).[2] The draft guidance describes conditions under which FDA does not generally intend to initiate enforcement action against State-licensed pharmacies, licensed veterinarians, and facilities registered as outsourcing facilities under section 503B of the FD&C Act (outsourcing facilities) that compound animal drugs from bulk drug substances.

For pharmacies, these conditions include receipt of a valid prescription for a compounded drug from a licensed veterinarian for an individually identified animal patient before the

[1] FDA regulations define ''bulk drug substance'' as ''any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.'' 21 CFR 207.3(a)(4). ''Active ingredient'' is defined as ''any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.'' 21 CFR 210.3(b)(7). Any component other than an active ingredient is an ''inactive ingredient.'' See 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products commonly include flavorings, dyes, diluents, or other excipients.

[2] GFI #230 can be found at *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm.*

facility compounds the drug (with some limited compounding of an animal drug product in advance of receipt of a prescription in quantities based on a history of receipt of patient-specific prescriptions for that drug product). FDA recognizes that there may be some limited circumstances in which a drug compounded from one or more bulk drug substances should be available to a veterinarian for office use and is developing a list of such animal drug products and the bulk drug substances needed to make them applicable to drugs compounded by facilities registered as outsourcing facilities under section 503B of the FD&C Act. The draft guidance proposes that outsourcing facilities compound animal drugs only from bulk drug substances that will be listed in Appendix A of the final guidance, either pursuant to a veterinarian's order or pursuant to a patient-specific prescription. When a facility registered as an outsourcing facility under section 503B of the FD&C Act uses the listed bulk drug substances to make the specified drug products pursuant to an order from a licensed veterinarian without a prescription for an individually identified animal, FDA does not intend to take action under sections 512(a), 501(a)(5) (21 U.S.C. 351(a)(5)), 502(f), and 501(a)(2)(B) as long as such compounding is done in accordance with any associated conditions described in GFI #230. Although an outsourcing facility may fill a veterinarian's order for compounded animal drugs using bulk drug substances listed on Appendix A without obtaining prescriptions for individually identified animal patients, drugs produced by outsourcing facilities remain subject to the requirements in section 503(f) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a compounded drug to the owner or caretaker of an animal patient without a prescription for that individually identified animal patient.

This list only applies to outsourcing facilities. This list does not limit what bulk drug substances State-licensed pharmacies or licensed veterinarians can use in compounding drugs in accordance with the conditions set forth in the draft guidance, including the condition pertaining to obtaining a patient-specific prescription.

FDA intends to include a bulk drug substance on Appendix A only when all of the following criteria are met:

- There is no marketed approved, conditionally approved, or index-listed animal drug that can be used as labeled to treat the condition;
- there is no marketed approved animal or human drug that could be used under section 512(a)(4) or (a)(5) of the FD&C Act and part 530 (addressing extra-label use of approved animal and human drugs) to treat the condition;
- the drug cannot be compounded from an approved animal or human drug;
- immediate treatment with the compounded drug is necessary to avoid animal suffering or death; and
- FDA has not identified a significant safety concern specific to the use of the bulk drug substance to compound animal drugs (under the listed conditions and limitations).

Inactive ingredients need not appear on Appendix A to be used in compounding animal drug products.

II. Request for Nominations

A. Active Ingredients

You may nominate specific bulk drug substances for inclusion on the list in Appendix A. Nominations will only be evaluated if they are for specific ingredients that meet the definition of a bulk drug substance in § 207.3(a)(4) (21 CFR 207.3(a)(4)). Nominated substances that do not meet this definition will not be included on the list.

To determine if a bulk drug substance should be included in Appendix A, FDA needs the following information about the bulk drug substance being nominated and the animal drug product(s) that will be compounded using such substance:

1. Confirmation That the Nominated Substance Is a Bulk Drug Substance

A statement that the nominated substance is an active ingredient that meets the definition of ''bulk drug substance'' in § 207.3(a)(4), and an explanation of why the substance is considered an active ingredient when it is used in the identified compounded drug product(s), citing to specific sources that describe the active properties of the substance.

2. General Background on the Bulk Drug Substance

- Ingredient name;
- chemical name;
- common name(s); and
- identifying codes, as available, from FDA's Unique Ingredient Identifiers used in the FDA/U.S. Pharmacopeial Convention (USP) Substance Registration System, available at *http://fdasis.nlm.nih.gov/srs/.* Because substance names can vary, this code, where available, will be used by the Agency to confirm the exact substance nominated and to identify multiple nominations of the same substance so the information can be reviewed together.
- Chemical grade of the ingredient;
- description of the strength, quality, stability, and purity of the ingredient;
- information about how the ingredient is supplied (*e.g.,* powder, liquid); and
- information about recognition of the substance in foreign pharmacopeias and the status of its registration(s) in other countries, including whether information has been submitted to USP for consideration of monograph development.

B. Information on the Animal Drug Products That Will Be Compounded With the Bulk Drug Substance

- Information about the dosage form(s) into which the bulk drug substance will be compounded;
- information about the strength(s) of the compounded product(s); and
- information about the anticipated route(s) of administration of the compounded product(s).

C. Need for the Animal Drug Products That Will Be Compounded With the Bulk Drug Substance

For FDA to be able to meaningfully evaluate a substance, the information provided must be specific to the particular substance nominated and animal drug product to be compounded. A ''boilerplate'' or general explanation of need for compounding with bulk drug substances will not enable FDA to conduct an adequate review. Unless adequate supporting data are submitted for a bulk drug substance, FDA will be unable to consider it for inclusion in Appendix A.

Prescribers of compounded animal drug products may be in the best position to explain why a particular bulk drug substance meets the criteria for including a bulk drug substance on Appendix A and are encouraged to provide data in support of a nomination. The following information about need is necessary to provide adequate support for nominations to the Appendix A list:

- A statement identifying the species and condition(s) that the drug product to be compounded with the nominated bulk drug substance is intended to treat;
- a bibliography of safety and efficacy data for the drug compounded using the nominated substance, if available,[3] including any relevant peer-reviewed veterinary literature;
- a list of animal drug products, if any, that are approved, conditionally approved, or index listed for the

[3] FDA recognizes that the available safety and efficacy data supporting consideration of a bulk drug substance for inclusion on the list may not be of the same type, amount, or quality as is required to support a new animal drug application.

condition(s) in the species that the drug compounded with the nominated substance is intended to address;

- if there are FDA-approved or index listed drug products that address the same conditions in the same species, an explanation, supported by relevant veterinary literature, of why a compounded drug product is necessary (*i.e.,* why the approved drug product is not suitable for a particular patient population);
- a review of the veterinary literature to determine whether there are FDA-approved animal or human drugs that could be prescribed as an extra-label use under section 512(a)(4) and (a)(5) of the FD&C Act and part 530 to treat the condition(s) in the species that the drug compounded with the nominated substance is intended to address;
- if the bulk drug substance is an active ingredient in an approved animal or human drug, an explanation, supported by appropriate scientific data, of why the animal drug product cannot be compounded from the approved drug under 21 CFR 530.13(b);
- an explanation, supported by relevant veterinary literature, of why the animal drug product to be compounded with the nominated bulk drug substance must be available to the veterinarian for immediate treatment to avoid animal suffering or death. Nominations should include specific information documenting that animal suffering or death will result if treatment is delayed until a compounded animal drug can be obtained pursuant to a prescription for an individually identified animal; and
- a discussion of any safety concerns associated with use of the nominated bulk drug substance or finished compounded product for the condition(s) in the species that the compounded drug is intended to address. If there are any safety concerns, an explanation, supported by veterinary literature, of why the concerns should not preclude inclusion of that bulk drug substance on Appendix A.

D. Nomination Process

For efficient consolidation and review of nominations, nominators are encouraged to submit their nominations in a format that explicitly addresses each item previously listed in the order that they appear. To consider a bulk drug substance for inclusion in Appendix A, FDA must receive adequate supporting data for the substance. FDA cannot guarantee that all drugs nominated during the nomination period will be considered for inclusion on Appendix A prior to its initial publication. Nominations that are not evaluated during this first phase will receive consideration for later addition to Appendix A.

Individuals and organization may petition FDA to make additional amendments to Appendix A after it is published, in accordance with § 10.30.

Interested persons may submit either electronic nominations to *http://www.regulations.gov* or written nominations to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of nominations. Identify nominations with the docket number found in the brackets in the heading of this document. Received nominations 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.*

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11983 Filed 5–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–D–1176 and FDA–2003–D–0202]

Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability; Withdrawal of Compliance Policy Guide; Section 608.400 Compounding of Drugs for Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI) #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' The draft guidance describes FDA's policies with regard to compounding animal drugs from bulk drug substances. When final, the guidance will reflect FDA's current thinking on the issues addressed by the guidance.

FDA is also announcing the withdrawal of the compliance policy guide (CPG) entitled ''Section 608.400 Compounding of Drugs for Use in Animals,'' which was issued in July 2003. This 2003 CPG is being withdrawn because it is no longer consistent with FDA's current thinking on the issues it addresses.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the 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 17, 2015. Submit written or electronic comments on the proposed collection of information by August 17, 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 request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

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

FOR FURTHER INFORMATION CONTACT: *With regard to this draft guidance:* Division of Compliance, Center for Veterinary Medicine, Food and Drug Administration (HFV–230), 7519 Standish Pl., Rockville, MD 20855, 240–402–7001, *CVMCompliance@fda.hhs.gov.*

With regard to the proposed collection of information: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE–14526, Silver Spring, MD 20993–0002; *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Draft Guidance

FDA is announcing the availability of a draft GFI #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' The draft guidance provides information to compounders of animal drugs and other interested stakeholders on FDA's application of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to the compounding of animal drugs from bulk drug substances.[1]

[1] FDA regulations define ''bulk drug substance'' as ''any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.'' 21 CFR 207.3(a)(4). ''Active ingredient'' is defined as ''any component that is intended to furnish