

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2014-N-0998]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, "Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring" 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 and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On January 08, 2015, the Agency submitted a proposed collection of information entitled, "Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0409. The approval expires on April 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: May 13, 2015.

Leslie Kux,*Associate Commissioner for Policy.*

[FR Doc. 2015-12078 Filed 5-18-15; 8:45 am]

BILLING CODE 4164-01-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2011-N-0802]

Exploring Naloxone Uptake and Use; Public Meeting; Request for Comments**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, in collaboration with the National Institutes on Drug Abuse, the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and the Health Resources and Services Administration, will hold a public meeting to discuss increasing the use of naloxone to reduce the incidence of opioid drug overdose fatalities. During the meeting, academic and government experts, industry representatives, and patient advocates will discuss which populations are at-risk for opioid drug overdose and how we can work together to encourage the use of naloxone to reduce the risk of overdose from opioid drugs.

Date and Time: The public meeting will be held on July 1, 2015, from 8 a.m. to 5 p.m. and on July 2, 2015, from 8 a.m. to 3 p.m. The open public hearing will be held between 1 p.m. and 2 p.m. on July 1, 2015, and between 1 p.m. and 2 p.m. on July 2, 2015, during which speaker testimony will be accepted. We will try to accommodate all persons who wish to testify; however, the duration of each speaker's testimony may be limited by time constraints. Those wishing to participate in the open public hearing should limit their remarks to issues related to the uptake of naloxone both in conventional medical settings and outside of those settings to reduce the incidence of opioid drug overdose fatalities.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002.

Contact Person: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3519, Mary.Gross@fda.hhs.gov; or Georgiann Ienzi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002,

301-796-3515, Georgiann.Ienzi@fda.hhs.gov.

Registration: If you wish to attend the public meeting or provide testimony during the open public hearing, please email your registration to NaloxoneWorkshop@fda.hhs.gov by June 22, 2015. Those without email access may register by contacting one of the contact persons (see *Contact Persons*). When registering, please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Registrants will receive confirmation once they have been accepted for the public meeting. Onsite registration on the day of the public meeting will be permitted based on space availability. If registration reaches maximum capacity, FDA will post a notice closing registration for the public meeting at: <http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm>.

Comments: Submit either electronic or written comments by September 1, 2015. Submit electronic comments 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. 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>. If you need special accommodations due to a disability, contact Mary Gross or Georgiann Ienzi (see *Contact Persons*) at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:**I. Introduction**

The number of prescriptions filled for opioid drugs has increased drastically in recent years. In 2009 nearly 257 million prescriptions were written for opioid drugs in the United States. This number rose to nearly 260 million in 2012. The increased availability of opioid drugs appears to be contributing significantly to abuse and overdose in the United States. In 2013 there were approximately 16,235 deaths from overdose involving opioid drugs. That same year, there were 8,257 deaths from overdose involving heroin.

Naloxone, a mu-opioid antagonist, is a medication that can rapidly reverse the overdose of both prescription opioid

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.

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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 substances¹ 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>.