



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Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability; Withdrawal of Compliance Policy Guide; Section 608.400 Compounding of Drugs for Use in Animals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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI) #230 entitled “Compounding Animal Drugs from Bulk Drug Substances.” The draft guidance describes FDA’s policies with regard to compounding animal drugs from bulk drug substances.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 This 2003 CPG is being withdrawn because it is no longer consistent with FDA’s current thinking on the issues it addresses.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you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by

[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit written or electronic comments on the proposed collection of information by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance, including comments regarding the proposed collection of information, to 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 Submit written comments on the draft guidance, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630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FOR FURTHER INFORMATION CONTACT: With regard to this draft guidance: Division of Compliance, Center for Veterinary Medicine, Food and Drug Administration (HFV-230), 7519 Standish Pl., Rockville, MD 20855, 240-402-7001,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; PRASStaff@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

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 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.

This draft guidance does not address the compounding of animal drugs from approved animal or human drugs pursuant to the extra-label provisions of the law, nor does it address 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.

repackaging of approved animal drugs. FDA is considering whether guidance is needed on those issues, and if so, will publish separate guidances. In section III, FDA is asking for comment on specific questions about several issues including the practice of compounding from approved animal and human drugs and the repackaging of drugs for animal use to help determine whether additional guidance is necessary on these topics.

This 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. The draft guidance provides that FDA does not generally intend to take action under sections 512(a), 501(a)(5) (21 U.S.C. 351(a)(5)), 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), and 502(f)(1) of the FD&C Act if a State-licensed pharmacy or a licensed veterinarian compounds drugs intended for use in animals from bulk drug substances in accordance with all of the applicable conditions set out in the guidance. In addition, the draft guidance provides that FDA does not generally intend to take action under sections 512(a), 501(a)(5), and 502(f)(1) of the FD&C Act if the drug product is compounded from a bulk drug substance by an outsourcing facility and that meets all of the applicable conditions set out in the guidance, and the drug product is compounded from a bulk drug substance that appears on Appendix A of the draft guidance.

Importantly, the draft guidance provides that FDA generally intends to enforce all other adulteration and misbranding provisions of the FD&C Act against entities compounding animal drugs from bulk drug substances.

To ensure FDA can timely identify and address safety issues related to animal drugs compounded from bulk drug substances, one of the conditions, if met, under which FDA does

not generally intend to take action for violations of the provisions described previously is that State-licensed pharmacies and veterinarians report any product defect or serious adverse event associated with animal drugs they compound from a bulk drug substance to FDA, within 15 days of becoming aware of them, using Form FDA 1932a. FDA intends to use these adverse event reports to identify animal drugs compounded from bulk drug substances that present serious risks to animal health. Unlike for human drugs, there are no State Departments of Health or Federal Agencies, such as the Centers for Disease Control and Prevention (CDC), which are responsible for identifying and tracing the source of injury and/or disease in animals. Adverse event reporting regarding drugs compounded from bulk drug substances by compounding pharmacies and veterinarians will provide a mechanism for FDA to identify and possibly prevent adverse events associated with compounded animal drugs. This is another topic on which we are requesting specific comment in section III.

Elsewhere in this issue of the Federal Register, FDA is publishing a notice soliciting nominations for bulk drug substances that should be included in Appendix A, “List of Bulk Drug Substances That May Be Used By an Outsourcing Facility to Compound Drugs for Use in Animals.” The notice also describes the information that should be provided to the Agency in support of such nominations.

II. Withdrawal of 2003 Compliance Policy Guide

In a notice published in the Federal Register of July 14, 2003 (68 FR 41591), FDA announced the availability of CPG Section 608.400 of the Compliance Program Guidance Manual entitled, “Compounding of Drugs for Use in Animals.” This document is being withdrawn because it is no longer consistent with FDA’s current thinking on the issue it addresses. The current CPG does not focus on the three main concerns FDA has about animal

drug compounding: compounding copies of approved animal or human drugs from bulk drug substances, compounding for food-producing animals from bulk drug substances, and compounding office stock from bulk drug substances. Because the CPG does not reflect FDA's current thinking, to leave it in effect until this draft guidance is finalized may confuse stakeholders about FDA's current enforcement priorities. Stakeholders should be aware that, until this draft guidance is finalized, FDA intends to look at the totality of the circumstances when determining whether to take enforcement action for unlawful animal drug compounding activities.

III. Specific Topics for Comment

In addition to comments on the draft guidance as written, we are specifically requesting comments on the following issues:

- Should the final guidance address the issue of FDA-approved animal and human drugs that are in shortage or are otherwise unavailable (e.g., disruptions in the manufacture or supply chain; business decisions to stop marketing the drug; drug is subject to Agency action based on safety, effectiveness, or manufacturing concerns)? If so:
 - How should these situations be addressed in the final guidance?
 - How should the final guidance define the terms "shortage" and "unavailable"?
 - What criteria should FDA use to determine if an approved animal or human drug is in shortage or otherwise unavailable?
- Do United States Pharmacopeia and National Formulary (USP-NF)² chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if

² Chapters <795> "Pharmaceutical Compounding--Nonsterile Preparations" and <797> "Pharmaceutical Compounding--Sterile Preparations" can be found in the combined United States Pharmacopeia and National Formulary (USP-NF), available at <http://www.usp.org/>.

not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians?

- Should licensed veterinarians be able to sell or transfer an animal drug compounded from bulk drug substances by a State-licensed pharmacy or an outsourcing facility to owners or caretakers of animals under the veterinarian's care?
- How should FDA apply the condition to identify an individual patient when it is not possible to identify an individual animal (e.g., koi in a koi pond)?
- Should the final guidance include a condition on the amount or percentage of compounded animal drugs that a pharmacy or outsourcing facility can ship in interstate commerce? If so, what would a reasonable amount be?
- Should facilities registered as outsourcing facilities under section 503B of the FD&C Act be able to compound animal drugs from bulk drug substances that do not appear on Appendix A for an individually identified animal patient under conditions similar to those applicable to state-licensed pharmacies (i.e., the conditions contained in section III.A. of the draft guidance)?
- Is additional guidance needed to address the repackaging of drugs for animal use?
 - How widespread is the practice of repackaging drugs for animal use?
 - What types of drugs are repackaged for animal use, and why are they repackaged?
 - Have problems been identified with repackaged drugs for animal use?
- Is additional guidance needed to address the compounding of animal drugs from approved animal or human drugs under section 512(a)(4) or (a)(5) of the FD&C Act and part 530?
- Is additional guidance needed to address the compounding of animal drugs from bulk drug substances for food-producing animals?

- As one condition under which FDA does not generally intend to take action for certain violations of the FD&C Act if this and the other conditions are followed, FDA is proposing that State-licensed pharmacies and veterinarians report any product defect or serious adverse event associated with animal drugs they compound from bulk drug substances to FDA within 15 days of becoming aware of the product defect or serious adverse event. Outsourcing facilities are required to report adverse events associated with the drugs they compound. FDA believes it is important to receive this information from State-licensed pharmacies and veterinarians because there are no other State Departments of Health or Federal Agencies (e.g., the CDC) charged with identifying and tracing animal injuries or disease associated with an animal drug compounded by these entities. FDA has the following specific questions with respect to this proposed condition:
 - How many State-licensed pharmacies and veterinarians compound animal drugs from bulk drug substances and would potentially be reporting product defects and serious adverse events to FDA?
 - Are State-licensed pharmacies and veterinarians reporting the same or similar information to any State regulatory agency (e.g., State boards of pharmacy, State boards of veterinary medicine)? If so, how many reports on average does each State-licensed pharmacy and veterinarian submit to these State agencies each year?
 - For purposes of the guidance, how should FDA define the terms “product defect” and “serious adverse event”?
 - Can FDA achieve the same objective of identifying and tracing the source of injuries or disease associated with an animal drug compounded from a bulk drug substance

through means other than product defect and serious adverse event reporting, and if so, what other means? For example, would reports of product defects alone achieve the same objective?

IV. 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 current thinking of FDA on compounding animal drugs from bulk drug substances. 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.

V. Paperwork Reduction Act of 1995

This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal Agencies to provide a 60-day notice in the Federal Register for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed

collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Compounding Animal Drugs from Bulk Drug Substances (OMB Control Number 0910-NEW)

Description of Respondents: The proposed collection of information would affect State-licensed pharmacies, licensed veterinarians, and outsourcing facilities that compound animal drugs from bulk drug substances.

Description: This draft guidance describes FDA's current thinking regarding compounding animal drugs from bulk drug substances and describes the conditions under which FDA does not generally intend to take action for violations of the following sections of the FD&C Act: 512, 501(a)(5), 502(f)(1), and, where specified, 501(a)(2)(B), when a State-licensed pharmacy, licensed veterinarian, or an outsourcing facility compounds animal drugs from bulk drug substances. The draft guidance provides three sets of conditions, one for each entity: State-licensed pharmacies, licensed veterinarians, and outsourcing facilities.

This draft guidance only addresses the compounding of animal drugs from bulk drug substances. It does not apply to the compounding of animal drugs from approved new animal or new human drugs. Such compounding can be conducted in accordance with the provisions of section 512(a)(4) and (5) of the FD&C Act and part 530. In addition, this guidance does not address the compounding of drugs intended for use in humans, which is addressed in other guidances.

FDA estimates the burden of this collection of information as follows:

Reporting

This draft guidance contains no new reporting provisions. This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information regarding voluntary reporting of adverse drug experiences or product/manufacturing defects on Form FDA 1932a, “Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report,” have been approved under OMB control number 0910-0284; the information collection provisions regarding establishment registration under section 510 of the FD&C Act (21 U.S.C. 360) have been approved under OMB control number 0910-0777. This draft guidance also refers to proposed collections of information regarding drugs made by an outsourcing facility during the previous 6-month period as described in FDA’s notice of November 24, 2014 (79 FR 69857), announcing the availability of a draft guidance entitled “Electronic Reporting for Human Drug Compounding Outsourcing Facilities.” The proposed collections of information in the draft guidance are subject to review by OMB under the PRA. As required by the PRA, FDA published an analysis of the information collection provisions of the draft guidance (79 FR 69857 at 69858) and intends to submit them for OMB approval.

Recordkeeping

Entities compounding animal drugs from bulk drug substances should keep adequate records to demonstrate that they are compounding such drugs in accordance with all of the applicable conditions described in the draft guidance. FDA tentatively concludes that it is usual and customary for State-licensed pharmacies, veterinarians, and outsourcing facilities to keep such records, and that this draft guidance imposes no additional recordkeeping burden beyond

those usual and customary for the respondents to this collection, with the exception of that described in section III.A.5. Nonetheless, table 1, row 1 provides a nominal estimate of potential recordkeeping burden that respondents may incur. FDA therefore specifically invites comment regarding whether these provisions impose any effort beyond that which would normally be incurred in absence of this draft guidance.

A condition set forth in section III.A.5. is that, if there is an FDA-approved animal or human drug with the same active ingredient(s), the pharmacy determines that the compounded drug cannot be made from the FDA-approved drug(s), and documents that determination.

Table 1.--Estimated Annual Recordkeeping Burden¹

Guidance Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
III; general recordkeeping beyond usual & customary	138,551	1	138,551	0.01 (30 seconds)	1,386
III.A.5; documentation of determination that compound drug cannot be made from the FDA-approved drug(s)	75,000	84.67	6,350,000	0.01 (30 seconds)	63,500
Total					64,886

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

For row 1, we base our burden estimates on the American Veterinary Medical Association's Market Research Statistics for 2013 for the total number of veterinarians in practice minus those veterinarians in food animal exclusive practice (63,500), the National Pharmacy Market Summary SK&A of March 2010 for the total number of pharmacy sites (75,000), and the number of registered outsourcing facilities as of March 20, 2015 (51), for a total of 138,551 respondents.³

³ The AVMA's Market Research Statistics--U.S. Veterinarians---2013 can be found at this URL: (<https://www.avma.org/KB/Resources/Statistics/Pages/Market-research-statistics-US-veterinarians.aspx>); the National Pharmacy Market Summary SK&A (March 2010) can be found at this URL: <http://www.skainfo.com/index.php>; and the list of registered outsourcing facilities can be found at this URL: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm>.

For row 2, we estimate that approximately 75,000 pharmacies will receive approximately 6,350,000 prescriptions for compounded animal drugs annually, and we also estimate that it will take approximately 30 seconds (0.01 hours) to document that the compounded drug cannot be made from the FDA-approved drug(s) for a total of 63,500 hours recordkeeping burden.

A condition set forth in section III.A.2. of the draft guidance is that State-licensed pharmacies can compound a drug in advance of receipt of a prescription in a quantity that does not exceed the amount of drug product that the State-licensed pharmacy compounded pursuant to patient-specific prescriptions based on a history of receipt of such patient-specific prescriptions for that drug product over any consecutive 14-day period within the previous 6 months. The records necessary for a State-licensed pharmacy to review to determine that its compounding practices are within the condition set forth in section III.A.2 of the draft guidance are records that State-licensed pharmacies would already be keeping as part of usual and customary business practice; therefore, no burden has been estimated for the recordkeeping associated with this condition.

This draft guidance also refers to proposed collections of information currently undergoing the process of OMB review under the PRA. Recordkeeping by outsourcing facilities, described in the draft guidance for industry, “Current Good Manufacturing Practice-- Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act” announced July 2, 2014 (79 FR 37743), will be reviewed by OMB in response to an information collection request associated with that guidance.

Third-party disclosure:

Prescriptions or orders for drugs compounded from bulk

This draft guidance contains new third-party disclosures as reported in table 2. Row 1

reflects a potential burden associated with section III.C.9. regarding the following condition: The veterinarian’s prescription or order states, in addition to the species, the condition(s) for which the substance is listed in Appendix A. At this time, however, FDA has no data upon which to base an estimated number of prescriptions or orders to outsourcing facilities until the referenced list of bulk drugs (Draft Guidance; Appendix A) is finalized. For purposes of this analysis, however, we are providing an estimate of 1 as a placeholder.

In section III.A.4., the draft guidance sets forth the following condition: If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug, there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an identified individual patient that produces a clinical difference for that identified individual patient, as determined by the veterinarian prescribing the compounded drug for his/her patient under his/her care. If the drug contains a bulk drug substance that is a component of a marketed FDA-approved animal or human drug, the prescription or documentation accompanying the prescription contains a statement that the change between the compounded drug and the FDA-approved drug produces a clinical difference for the individual identified patient. For example, the veterinarian could state that, “This compounded drug is needed to treat [specifically identified patient] because the approved drug product(s) cannot be divided or diluted into the small dose required.”

Table 2.--Estimated Annual Third-Party Disclosure Burden¹

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
III.C.9; documentation of condition to be treated	1	1	1	0.017 (1 minute)	0.017
Statements on prescription (Section III.A.4 of the draft guidance)	63,500	100	6,350,000	0.017 (1 minute)	107,950
Total					107,950

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

For row 2, we estimate that approximately 63,500 veterinarians will, on average, each produce approximately 100 prescriptions for compounded animal drugs annually for a total of 6,350,000 prescriptions. We also estimate that it will take approximately 1 minute (0.017 hours) to include the statement discussed in section III.A.4 of the draft guidance on each prescription for a total of 107,950 hours third-party disclosure burden, as reported in table 1.

It is usual and customary for licensed veterinarians to write prescriptions in the normal course of their activities. The conditions set forth in the guidance require veterinarians to include certain information on prescriptions for animal drugs compounded from bulk substances. It is usual and customary for veterinarians to include much of this information (except as noted previously); therefore, the time it would take to provide this information on prescriptions or documents accompanying prescriptions is not included in the burden estimate reported in table 2.

Sections III.A.3 and III.A.6.b of the draft guidance set forth the conditions that the following statements appear verbatim on or with prescriptions for animal drugs compounded from bulk drug substances:

- “This patient is not a food-producing animal.” (Section III.A.3).
- “There are no FDA-approved animal or human drugs that can be used as labeled or in an extra-label manner under section 512(a)(4) and (5) and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed.” (Section III.A.6.b).

In addition, section III.C.3 of the draft guidance sets forth the condition that the following statement appears verbatim on or with prescriptions or orders for animal drugs compounded by outsourcing facilities from bulk drug substances listed on Appendix A:

- “This drug will not be dispensed for or administered to food-producing animals.”
(Section III.C.3).

We tentatively conclude that these statements are “public disclosures of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)) and are therefore not subject to review by OMB under the PRA. Thus, the time it would take to provide this information is not included in the burden estimate reported in table 2.

Labeling of drugs compounded from bulk drug substances

The draft guidance sets forth conditions for the labeling of animal drugs compounded from bulk drug substances. The draft guidance indicates in sections III.A.11 and III.B.9 that, to meet the conditions of the guidance, State-licensed pharmacies and licensed veterinarians include on the label of any compounded drug: The species of the intended animal patient, the name of the animal patient, and the name of the owner or caretaker of the animal patient. It is usual and customary for State-licensed pharmacies and licensed veterinarians to include such information on the labels of compounded drugs in the normal course of their activities; thus, the time it would take to provide this information is not included in the burden estimate reported in table 2.

In addition, the draft guidance indicates in section III.C.10. that, to meet the conditions of the guidance, outsourcing facilities include on the label of any compounded animal drug pursuant to a specific prescription or order: The active ingredient; the dosage form, strength, and flavoring, if any; direction for use, as provided by the veterinarian prescribing or ordering the drug; the quantity or volume, whichever is appropriate; the lot or batch number of the drug; special storage and handling instructions; the date the drug was compounded; the beyond use date of the drug; the name of the veterinarian prescribing or ordering the drug; the inactive

ingredients; and the address and phone number of the outsourcing facility that compounded the drug. It is usual and customary for outsourcing facilities to include such information on the labels of compounded drugs in the normal course of their activities; thus, the time it would take to provide this information is not included in the burden estimate reported in table 2.

The draft guidance indicates in section III.C.10 that, to meet the conditions of the guidance, outsourcing facilities compounding animal drug from bulk drug substances for office use in veterinary practices include on the label of any compounded drug these four statements:

- “Not for resale.”
- “For use only in [fill in species and any associated condition or limitation listed in Appendix A].”
- “Compounded by [name of outsourcing facility].”
- “Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a.”

We tentatively conclude that these four label statements are “public disclosures of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)) and are therefore not subject to review by OMB under the PRA. Thus, the time it would take to provide this information is not included in the burden estimate reported in table 2.

This draft guidance also refers to previously approved collections of information. A condition set forth in sections III.A.7., III.B.6, and III.C.5 is that any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (including a foreign establishment that is registered under section 360(i) of the FD&C Act) and is accompanied by a valid certificate of analysis. The information collection related to the

disclosure of the certificate of analysis is approved under OMB control number 0910-0139.

Before the proposed information collection provisions contained in this draft guidance become effective, we will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the proposed information collection provisions. 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.

VI. Comments

Interested persons may submit either electronic comments regarding this draft guidance 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 Docket No. FDA-2015-D-1176. 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>.

VII. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/cm042450.htm> or <http://www.regulations.gov>.

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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