good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. 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.

This guidance is intended to help owners of fish and fishery products, or their representatives, interested in bringing adulterated products into compliance with the Federal Food, Drug, and Cosmetic Act by means of segregating non-violative product from adulterated product. Specifically, this document provides guidance on:

- Segregation based on a production-related rationale supported by production records or information identifying the cause of the adulteration along with sampling and testing to confirm that the segregation was successful; or
- Segregation based on the results of statistically significant sampling and testing.

In the **Federal Register** of September 17, 2019 (84 FR 48935), we announced a draft guidance for industry entitled ''Reconditioning of Fish and Fishery Products by Segregation'' and gave interested parties an opportunity to submit comments by November 18, 2019, for us to consider before beginning work on the final version of the guidance. We received comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include the addition of a detailed explanation for our more robust sampling recommendations. The guidance announced in this notice finalizes the draft guidance dated September 2019.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 1.94(b) and 21 CFR 1.95(a) and (b) using Form FDA 766 have been approved under the OMB control number 0910–0025.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07979 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4626]

Lists of Bulk Drug Substances for Compounding: Office Stock Drugs for Use in Nonfood-Producing Animals or Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing updated information for interested parties to nominate bulk drug substances or renominate bulk drug substances that were previously nominated without adequate supporting information, for inclusion on a list of bulk drug substances for compounding certain animal drugs without a patient specific prescription (*i.e.,* office stock) for use in nonfood-producing animals or for inclusion on a list of compounded drugs for use as antidotes for food-producing animals or for use as sedatives or anesthetics for free-ranging wildlife species, as described in the guidance for industry #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' Individuals may also comment on bulk drug substances that have been reviewed by FDA and added to these lists, or nominations that are currently under FDA review.

DATES: You may submit either electronic or written nominations and comments at any time.

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

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, 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 in the following ways:

- *Mail/Hand Delivery/Courier (for 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–2018–N–4626 for ''Lists of Bulk Drug Substances for Compounding: Office Stock Drugs for Use in Nonfood-Producing Animals or Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species.'' 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 nominations and 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.

FOR FURTHER INFORMATION CONTACT: Cindy Burnsteel, Office of Surveillance and Compliance (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, Rockville, MD 20855, 240–402–7011, *cvmcompliance@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Except with respect to the limited exemption provided by the Federal Food, Drug, and Cosmetic Act (FD&C Act) described in the following paragraph, statutory provisions applicable to manufactured animal drugs under the FD&C Act also apply to animal drugs compounded from bulk drug substances (also known as active pharmaceutical ingredients (APIs)).[1]

Sections 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 compounded animal drugs made from already FDA-approved animal or human drugs. Such use is considered an extralabel use. The FD&C Act provides that a compounded drug is exempt from the approval requirements in section 512(a) of the FD&C Act and requirements for adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) if it meets the conditions set out in the statute and the extralabel use regulations at 21 CFR part 530.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of guidance for industry #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances'' (GFI #256).[2] Animal drugs compounded from bulk drug substances by pharmacists and veterinarians violate the FD&C Act because they do not meet the requirements for approval, current good manufacturing practice (CGMP) requirements, or adequate directions for use. The guidance describes circumstances under which FDA generally does not intend to take action against veterinarians, or pharmacists in either State-licensed pharmacies or Federal facilities, who compound animal drugs from bulk drug substances. FDA does not intend to take action under sections 512(a), 502(f), and 501(a)(2)(B) and (a)(5) (21 U.S.C 351(a)(2)(B) and (a)(5)) of the FD&C Act under the circumstances described in GFI #256.

II. Nominating Bulk Drug Substances

In a **Federal Register** notice published November 19, 2019, FDA established a public docket (FDA–2018–N–4626) so that interested parties could nominate bulk drug substances to a list of bulk drug substances for compounding office stock drugs for use in nonfood-producing animals or antidotes for food-producing animals (the List) and comment on nominated and evaluated bulk drug substances (the 2019 request for nominations notice).

In conjunction with finalizing GFI #256, FDA is expanding nominations to include drugs compounded for use as sedatives or anesthetics for free-ranging wildlife species. We are also reorganizing the List into two separate Lists:

1. The List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals[3] and
2. The List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species[4]

Interested parties can nominate bulk drug substances to either List, renominate bulk drug substances with adequate supporting information that were previously nominated without adequate supporting information, or comment on previously nominated bulk drug substances that have been added to a List. This docket will remain open indefinitely so that individuals may nominate and comment on bulk drug substances at any time.

A. When will FDA include a bulk drug substance on either of the Lists?

FDA intends to include a bulk drug substance on either of the Lists when:

1. There is no marketed FDA-approved, conditionally approved, or indexed animal drug(s) that can be used as labeled to treat the condition;

2. There is no marketed FDA-approved, conditionally approved, or indexed animal or human drug(s) with the same active ingredient(s) that could be used in an extralabel manner to treat the condition; and

3. FDA has not identified a significant safety concern specific to the use of the bulk drug substance in animals.

For bulk drug substances used to compound drugs intended as office stock for nonfood-producing animals, in addition to 1 to 3 above:

4. Urgent treatment with the compounded drug is necessary to avoid animal suffering or death, or to protect public safety.

For bulk drug substances used to compound drugs intended for use as antidotes in food-producing animals or for use as sedatives or anesthetics for free-ranging wildlife species, in addition to 1 to 3 above:

5. There is sufficient scientific information for the prescribing veterinarian to determine appropriate withdrawal, withholding, or discard time(s) for meat, milk, eggs, or any food that might be derived from the treated animal(s).

[1] FDA regulations define ''bulk drug substance'' and ''active pharmaceutical ingredient'' as ''any substance that is intended for incorporation into a finished drug product and 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.'' The terms do not include intermediates used in the synthesis of the substance. 21 CFR 207.1. ''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.'' 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products commonly include flavorings, dyes, diluents, or other excipients.

[2] *https://www.fda.gov/media/132567/download.*

[3] Available at *https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals.*

[4] Available at *https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-drugs-use-food-producing-animals-or-free-ranging-wildlife.*

B. How do I submit a nomination for one of the Lists?

You may submit nominations and comments to the docket through *https://www.regulations.gov.* The information to support nominations can be uploaded as attachments to your comment. The docket number is FDA–2018–N–4626.

You may submit written submissions to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All submissions must include the Docket No. FDA–2018–N–4626 for ''Lists of Bulk Drug Substances for Compounding: Office Stock Drugs for Use in Nonfood-Producing Animals or Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species.''

C. What information should I submit with the nomination?

You may nominate specific bulk drug substances for inclusion on either of the Lists. Each bulk drug substance should be submitted to the docket as its own, separate nomination. Submissions to the docket containing more than one bulk drug substance will not be considered an adequate nomination and will not be reviewed. Nominated substances that do not meet the definition of a bulk drug substance will not be evaluated for inclusion on a List.

For FDA to evaluate a bulk drug substance for inclusion on a List, you should submit the following information about the bulk drug substance and the compounded animal drug in the nomination:

1. Description of the Bulk Drug Substance:

(a) Chemical name(s);

(b) common name(s);

2. Description of the Animal Drugs That Will be Compounded with the Nominated Bulk Drug Substance:

(a) Dosage form(s) into which the bulk drug substance will be compounded (*e.g.,* capsule, tablet, suspension);

(b) strength(s) of the compounded drug(s); and

(c) intended route(s) of administration of the compounded drug(s) (*e.g.,* oral, topical, injection, etc.).

3. Information Requested for FDA to Evaluate Bulk Drug Substances for Inclusion on a List:

(a) The species the drug to be compounded with the nominated bulk drug substance is intended to treat;

(b) The disease or condition(s) the drug to be compounded with the nominated bulk drug substance is intended to treat;

(c) If there is a marketed FDA-approved, conditionally approved, or indexed animal drug(s) that addresses the same condition(s) in the same species, an explanation of why a compounded drug is necessary (*e.g.,* why FDA-approved, conditionally approved, or indexed animal drug(s) is not suitable for a particular animal population);

(d) Confirmation that there is no marketed FDA-approved, conditionally approved, or indexed drug(s) that could be prescribed to treat the condition in the species that the drug compounded with the nominated substance is intended to address;

(e) If known by the nominator, if the bulk drug substance is an active ingredient in a marketed FDA-approved, conditionally approved, or indexed animal or human drug(s), an explanation of why the animal drug cannot be compounded from the marketed FDA-approved, conditionally approved, or indexed animal or human drug(s).

(f) If known by the nominator, a description of any human user or animal safety concerns associated with use of the nominated bulk drug substance or finished compounded drug for the condition(s) in the species that the compounded drug is intended to address. If there are concerns, an explanation of why the concerns should not preclude inclusion of that bulk drug substance on the List;

(g) For compounded drugs intended as office stock for nonfood-producing animals, an explanation of why the animal drug to be compounded with the nominated bulk drug substance is important to be available to the veterinarian for urgent treatment to avoid animal suffering or death, *e.g.,* why 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

(h) For compounded drugs intended for use as antidotes to treat toxicoses in food-producing animals, or as sedatives or anesthetics for free-ranging wildlife species, relevant scientific literature or other evidence that demonstrates that the prescribing veterinarian has a basis for determining appropriate withdrawal, withholding, or discard time(s) for meat, milk, eggs, or any food which might be derived from the treated animal(s).

4. Contact information for FDA should there be followup questions regarding the nomination.

D. What about drugs that have been nominated for one of the Lists and are still under review?

FDA identifies those bulk drug substances that have been nominated and under review at ''Bulk Drug Substances Currently Under Review.'' [5] At this time, FDA generally intends to refrain from taking enforcement action when these bulk drug substances currently under review are used to compound a finished drug as described in the nomination. Bulk drug substances will remain on ''Bulk Drug Substances Currently Under Review'' only during FDA's review of their nomination. If FDA completes its review and declines to place the bulk drug substance on a List based on the information provided, FDA will place the bulk drug substance on ''Bulk Drug Substances Reviewed and Not Listed''; [6] however, FDA will continue to accept and review any adequate additional information submitted by any party that supports the previously reviewed nomination. Should adequate additional information be provided such that FDA can conduct further substantial review, the bulk drug substance will again be placed on ''Bulk Drug Substances Currently Under Review.''

E. What happens when FDA approves or indexes a drug made with a bulk substance as described on one of the Lists?

FDA intends to remove a bulk substance from a List if a finished drug containing that substance in the appropriate dosage form and strength is approved or indexed. Please see ''Bulk Drug Substances Reviewed and Not Listed.''

F. What happens when FDA reviews a bulk drug substance and determines that it cannot be placed on a List because of insufficient information or because of other reasons (e.g., safety concerns)?

Please see ''Bulk Drug Substances Reviewed and Not Listed'' for those bulk drug substances that have been reviewed by FDA but are not on either List.

In a **Federal Register** notice published on May 19, 2015 (80 FR 28622), FDA invited all interested parties to nominate bulk drug substances for inclusion on a list of bulk drug substances that could be used by outsourcing facilities registered under the FD&C Act to compound animal drugs under the conditions described in draft GFI #230, ''Compounding Animal Drugs from Bulk Drug Substances'' (announced in the same issue of the

[5] Available at: *https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-currently-under-review.*

[6] Available at *https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-reviewed-and-not-listed.*

Federal Register (80 FR 28624)) (the 2015 request for nominations notice).

Although that draft guidance was subsequently withdrawn in November 2017, FDA received over 30 comments containing nominations for multiple bulk drug substances in response to the 2015 request for nominations notice. FDA's approach for determining whether to include a bulk drug substance on the list described in the 2015 request for nominations notice was substantially the same as the approach described above for including a bulk drug substance on the ''List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals'' in accordance with GFI #256. Therefore, and in keeping with our intention as stated in the 2019 request for nomination notice, the Agency is including certain of these nominated bulk drug substances on this List. For other of these nominated bulk drug substances, finished drugs containing the bulk drug substances in the appropriate dosage form and strength have subsequently been approved; thus, these nominated bulk drug substances will not appear on the List.

Some bulk drug substances were nominated in response to the 2015 request for nominations notice with insufficient supporting information. FDA subsequently searched for additional supporting information for these bulk substances, conducted further review, and added those with sufficient supporting information to the ''List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals.''

In addition, on its own initiative, FDA has identified certain bulk drug substances that are used in minor species. Several have been evaluated and are included on the ''List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals.'' Those identified bulk drug substances still under evaluation are included on ''Bulk Drug Substances Currently Under Review.'' As FDA continues to identify and evaluate bulk drug substances that are used in minor species, we also encourage outside nominations.

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08018 Filed 4–13–22; 8:45 am]

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 10(d) 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; Mechanisms of Memory and Sound Processing.

Date: April 26, 2022.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sepandarmaz Aschrafi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040D, Bethesda, MD 20892, (301) 451.4251, *Armaz.aschrafi@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: April 8, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07958 Filed 4–13–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

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: National Advisory Dental and Craniofacial Research Council.

Date: May 18, 2022.

Open: 10:00 a.m. to 1:30 p.m.

Agenda: Report of the Director, NIDCR and concept clearances.

Place: National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lynn M. King, Ph.D., Executive Secretary, Division of Extramural Activities, National Institute of Dental Craniofacial Research, 6701 Democracy Blvd., Room 960, Bethesda, MD 20892–4878, (301) 594–5006, *Lynn.King@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nidcr.nih.gov/about,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 8, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07957 Filed 4–13–22; 8:45 am]

BILLING CODE 4140–01–P