noncustodial parents, satisfaction with the child support program, and parent-child contact. Other recent evidence is from the Parents and Children Together Evaluation, which examined the effectiveness of four Responsible Fatherhood programs funded by ACF's Office of Family Assistance. The evaluation found that the programs improved aspects of fathers' parenting behavior, employment, and knowledge of the child support program. Two additional demonstrations, the Enhanced Transitional Jobs Demonstration and the Subsidized and Transitional Employment Demonstration, examined the effectiveness of subsidized employment. Four sites in the demonstrations focused on serving noncustodial parents. The evaluation found that subsidized employment programs in the study increased the earnings of noncustodial parents and increased the consistency of paying formal child support during the final year of the 30-month follow-up period.

2.0 Request for Information

Through this RFI, ACF is soliciting ideas and information from a broad array of stakeholders on improving nonresident parents' employment outcomes, including how to create a comprehensive, multi-system approach that addresses multiple barriers that nonresident parents face when trying to support their children. Although the primary aim of this RFI is to understand further how employment programs can increase nonresident parents' ability to economically support their children, we recognize that nonresident parents are parents first and may also face barriers to supporting their children emotionally. Consequently, we are not only interested in information and recommendations on programs that focus exclusively on employment services, but we are also interested in programs that provide employment services combined with parenting or other activities aimed at promoting father involvement and healthy relationships in children's lives.

The Evidence Act (Pub. L. 115–435) requires federal agencies to develop evidence-building plans to identify and address policy questions relevant to programs, policies, and regulations of the agency. Responses to this RFI will inform ACF's ongoing development of a learning and action agenda on employment programs for nonresident parents. This RFI is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of ACF or HHS.

We ask respondents to address the following questions. You do not need to address every question, and should focus on those where you have relevant expertise or experience. In your response, please provide a brief description of yourself or your organization before addressing the questions.

3.0 Key Questions

3.1 In your opinion, what are the core components necessary for an employment program to be effective for nonresident parents? Please provide evidence that supports your opinion.

3.2 In your opinion, what factors have either facilitated or hindered the implementation of employment programs for nonresident parents?

3.3 Please describe existing, promising employment programs/services for nonresident parents that may include, but are not limited to, work readiness training, occupational/sector-based training, job search assistance, subsidized employment, or other employment services. When describing the program, please include the following:

a. Target population,

b. Structure and organizational context of the program,

c. Roles and responsibilities of the lead agency and any partner agency,

d. Services provided, and

e. Any evidence of the program's effectiveness.

3.4 What role has job training, both in the classroom and on-the-job, played in effective employment programs for nonresident parents?

3.5 What role has activities aimed at parenting and promoting father involvement and healthy relationships in children's lives played in effective employment programs for nonresident parents?

3.6 To what extent do services need to vary depending on the subpopulation of nonresident parents being served? Please explain what services you believe are better suited for which subpopulations. Subpopulations could include, but are not limited to, noncustodial parents, parents with criminal records and/or a history of incarceration, young/teen parents, and parents with children by multiple partners, etc.

3.7 What are the key barriers that nonresident parents face when trying to secure or maintain employment to support their children financially? We are interested in hearing about both individual- and system-level barriers that nonresident parents may face to financially supporting their children, such as those related to transportation, education, housing, employment history, child access, child support debt, criminal record, fees/fines/restitution debt, substance use or mental health disorders, etc.

3.7.1 What specific approaches have you seen programs use to address these barriers? Please provide any evidence on the effectiveness of these approaches in improving parents' financial support for their children.

3.8 In your experience, what types of agencies or organizations should be active partners in an employment program for nonresident parents? Which type of agency is most successful in the lead role?

3.9 Please describe ways to create more systematic relationships between child support agencies and employment service providers that might increase the take-up of employment services among nonresidential parents or increase child support compliance among noncustodial parents in employment programs, etc.

3.10 If you are a government official or a practitioner, what additional information would you like to have about approaches to providing or implementing employment programs for nonresident parents?

3.11 What aspects of employment programs for nonresident parents would benefit from further evaluation?

3.12 What suggestions do you have for how federal, state, regional, tribal, and local governments could support the development of high-quality employment programs for nonresident parents and/or address gaps in current efforts?

Authority: Social Security Act § 413 (Title IV–A: Block Grants to States for the Temporary Assistance of Needy Families) [42 U.S.C. 613].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–25157 Filed 11–19–19; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4626]

List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: FDA is establishing a public docket 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 as antidotes for food-producing animals, as described in the draft guidance for industry #256, ''Compounding Animal Drugs from Bulk Drug Substances,'' when that guidance is finalized. Individuals may also comment on bulk drug substances that have been reviewed by FDA and added to this list, 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 ''List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals.'' 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Eric Nelson, Division of Compliance (HFV–230), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7001, *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.

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 draft guidance for industry #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances'' (GFI #256).[1] The draft guidance describes circumstances under which FDA, based on our current understanding of the risks of animal drugs compounded from bulk drug substances, does not intend to take action against pharmacists in either State-licensed pharmacies or Federal facilities, or veterinarians, who compound animal drugs from bulk drug substances. If the draft guidance is finalized, FDA would not intend to take action under sections 512(a), 501(a)(5), 502(f), and 501(a)(2)(B) of the FD&C Act so long as such compounding is done under the approach described in draft GFI #256.

II. Nominating Bulk Drug Substances

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

[1] Draft GFI #256 can be found at *https://www.fda.gov/animal-veterinary/guidance-industry/guidance-number.*

Drugs from Bulk Drug Substances'' (announced in the same issue of the **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 evaluating whether to include a bulk drug substance on the list described in the 2015 request for nominations notice is substantially the same as the approach below for including a bulk drug substance on the 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 antidotes for food-producing animals in accordance with FDA's draft guidance for industry #256 (the List). As a result, CVM intends to include on the List the eight bulk drug substances that FDA previously determined met the approach set out in the now withdrawn 2015 draft guidance. To the extent these substances and conditions of use meet the approach of the final guidance, FDA intends to include them on the List when the draft guidance is finalized.

- *Apomorphine hydrochloride—Indication:* For the induction of emesis in dogs. Dosage form: 6.25 mg subconjunctival tablets, 3.125–6.25 milligrams/milliliters (mg/ml) subconjunctival solution, and 2.5 mg/ml injectable solution.
- *Cisapride—Indication:* For the management of gastrointestinal motility disorders in cats. Dosage form: 2.5 & 5 mg oral tablets, 2.5 & 5 mg oral capsules, 5–10 mg/ml oral suspension.
- *Dipyrone—Indication:* For the treatment of severe, acute fever in dogs suffering from Shar-Pei Fever. Dosage form: 250 mg/ml and 500 mg/ml injectable solution.
- *Guaifenesin—Indication:* For muscle relaxation in the horse during anesthetic induction and/or surgery. Dosage form: 50 g soluble powder to be reconstituted into a solution for IV infusion with the addition of 500 ml (10%) or 1000 ml (5%) sterile diluent.
- *Miconazole nitrate—Indication:* For the treatment of fungal keratitis in horses. Dosage form: 1% or 2% miconazole nitrate ophthalmic solution or ophthalmic ointment.
- *Potassium bromide—Indication:* For initiation of treatment for seizures in dogs. Dosage form: 250 mg/ml oral solution.
- *Tacrolimus—Indication:* For treatment of dogs with keratoconjunctivitis sicca that is non-responsive to cyclosporine. Dosage form: 0.01–0.03% tacrolimus ophthalmic drops.
- *Metronidazole benzoate—Indication:* For the treatment of feline inflammatory bowel disease in cats. Dosage form: 80 mg/ml oral suspension.

The docket used to collect the previous nominations is now closed for comment. However, FDA is establishing a new public docket so that interested parties can nominate bulk drug substances, re-nominate bulk drug substances with adequate supporting information that were previously nominated without adequate supporting information, or comment on the eight previously nominated bulk drug substances that FDA intends to add to the List when the draft guidance is finalized. This docket will remain open indefinitely so that individuals may nominate and comment on bulk drug substances at any time.

When will FDA include a bulk drug substance on the list of bulk drug substances for compounding office stock drugs for use in nonfood-producing animals or antidotes for food-producing animals?

FDA intends to include a bulk drug substance on the List when:

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

2. There is no marketed FDA-approved animal or human drug that could be used in an extralabel manner under section 512(a)(4) or (a)(5) of the FD&C Act and part 530 to treat the condition;

3. The drug cannot be compounded from a legally marketed FDA-approved, conditionally approved, or indexed animal or human drug;

4. Immediate treatment with the compounded drug is necessary to avoid animal suffering or death; and

5. 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).

For bulk drug substances for compounding drugs intended for use as antidotes in food-producing animals in addition to the above:

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

How do I submit a nomination for the list?

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 ''List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals.''

What information should I submit with the nomination?

You may nominate specific bulk drug substances for inclusion on the List. 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. In addition, nominations will only be evaluated if they are for specific substances that meet the definition of a bulk drug substance.[2] Nominated substances that do not meet this definition will not be evaluated for inclusion on the List.

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

1. Confirmation That the Nominated Substance is a Bulk Drug Substance: A

[2] 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. In addition, for purposes of evaluating nominations, FDA considers bulk chemicals used to make antidotes intended to treat toxicoses in animals to be bulk drug substances.

statement that the nominated substance meets the definition of bulk drug substance.

2. Description of the Bulk Drug Substance:

(a) Chemical name(s);

(b) common name(s);

(c) chemical grade (*e.g.,* USP–NF, ACS, etc.);

(d) description of the strength, stability, purity; and

(e) how the bulk drug substance is supplied (*e.g.,* powder, liquid).

3. Description of the Animal Drugs That Will be Compounded With the 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).

4. Information Requested for FDA to Evaluate Bulk Drug Substances for Inclusion on the List:

(a) the species and condition(s) that the drug to be compounded with the nominated bulk drug substance is intended to treat;

(b) a bibliography of scientific literature containing safety and effectiveness data for the drug compounded using the nominated substance;

(c) a list of animal drugs, if any, that are FDA-approved, conditionally approved, or indexed for the condition(s) in the species that the drug compounded with the nominated substance is intended to address;

(d) if there are marketed FDA-approved, conditionally approved, or indexed drugs that address the same condition(s) in the same species, an explanation, supported by relevant scientific literature or other evidence, of why a compounded drug is necessary (*e.g.,* why the FDA-approved, conditionally approved, or indexed drug is not suitable for a particular animal population);

(e) confirmation, using supporting evidence, that there are no marketed FDA-approved animal or human drugs that could be prescribed in an extralabel manner under section 512(a)(4) and (a)(5) of the FD&C Act and 21 CFR part 530 to treat the condition(s) in the species that the drug compounded with the nominated substance is intended to address;

(f) If the bulk drug substance is an active ingredient in a marketed FDA-approved, conditionally approved, or indexed animal or human drug, an explanation, supported by appropriate scientific data or information, of why the animal drug cannot be compounded from the marketed FDA-approved, conditionally approved, or indexed animal or human drug.

(g) An explanation, supported by relevant scientific literature or other evidence, of why the animal drug 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

(h) 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, supported by scientific literature or other evidence, of why the concerns should not preclude inclusion of that bulk drug substance on the List.

(i) For compounded drugs intended for use as antidotes to treat toxicoses in food-producing animals, 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).

Dated: November 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25140 Filed 11–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5157]

2019 Public Meeting on Center for Drug Evaluation and Research Standard Core Sets: Clinical Outcome Assessments and Endpoints Grant Program; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''2019 Public Meeting on CDER Standard Core Sets: Clinical Outcome Assessments and Endpoints Grant Program.'' The purpose of the public meeting is to help ensure that as standard core sets of clinical outcome assessments (COAs) are developed as part of the FDA pilot grant program, the identified concepts, COAs, and endpoints reflect what is most important to patients and relevant to regulatory and potentially other stakeholder decision making. To facilitate this, stakeholders including patients, care partners, FDA reviewers, drug developers, other government and academic researchers, health care providers, health technology assessors and health payers are encouraged to attend the meeting.

DATES: The public meeting will be held on December 5, 2019, from 8:30 a.m. to 12 p.m. Submit either electronic or written comments on this public meeting by January 6, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 6, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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