

List of Subjects

21 CFR Parts 520, 522, and 529

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520, 522, 529, and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

- 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2640 [Amended]

- 2. In § 520.2640, in paragraphs (b)(1) and (d) remove “No. 000986” and in its place add “Nos. 000986 and 016592”; and in paragraph (b)(2) remove “Nos. 016592 and 061623” and in its place add “No. 061623”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

- 3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

- 4. In § 522.690, revise the section heading and paragraph (d)(2)(v) to read as follows:

§ 522.690 Dinoprost.

* * * * *

(d) * * *

(2) * * *

(v) Dinoprost injection as provided by No. 054771 in § 510.600(c) of this chapter may also be used concurrently with gonadorelin hydrochloride injection as in § 522.1077 and with progesterone intravaginal inserts as in § 529.1940 of this chapter.

* * * * *

- 5. In § 522.1077, revise paragraph (c)(1)(ii) to read as follows:

§ 522.1077 Gonadorelin hydrochloride.

* * * * *

(c) * * *

(1) * * *

(ii) For use with dinoprost injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows, administer to each cow 100 to 200 mcg gonadorelin by intramuscular injection, followed 6 to 8 days later by 25 mg dinoprost by intramuscular injection, followed 30 to

72 hours later by 100 to 200 mcg gonadorelin by intramuscular injection. Dinoprost injection as in § 522.690, provided by No. 054771 in § 510.600(c) of this chapter.

* * * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

- 6. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

- 7. In § 529.1940, revise paragraph (d), the second sentence in paragraph (e)(1)(i) and the last sentence in paragraph (e)(1)(iii) to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

* * * * *

(d) *Special considerations.* Product labeling shall bear the following warning: “Avoid contact with skin by wearing protective gloves when handling inserts. Store removed inserts in a sealable container until they can be disposed of in accordance with applicable local, state, and Federal regulations.”

(e) * * *

(1) * * *

(i) * * * When used for indications listed in paragraph (e)(1)(ii)(A) of this section, administer 25 mg dinoprost as a single intramuscular injection 1 day prior to insert removal (Day 6). * * *

* * * * *

(iii) * * * Dinoprost injection for use in paragraphs (e)(1)(ii)(A) and (e)(1)(ii)(B) of this section as in § 522.690 of this chapter, provided by No. 054771 in § 510.600(c) of this chapter.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

- 8. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.4 [Amended]

- 9. In paragraph (d) of § 558.4, in the “Category I” table, in the “Assay limits percent type A” column, in the entry for “Salinomycin”, remove “95–115” and in its place add “90–110”.

§ 558.76 [Amended]

- 10. In § 558.76, remove and reserve paragraph (d)(3)(vii).

§ 558.500 [Amended]

- 11. In § 558.500, in the table in paragraphs (e)(2)(viii) and (e)(2)(x), in the “Sponsor” column, remove

“000986” and in its place add “000986, 054771”.

Dated: July 24, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–17912 Filed 7–30–14; 8:45 am]

BILLING CODE 4164–01–P

MILLENNIUM CHALLENGE CORPORATION**22 CFR Part 1305**

[MCC FR 14–03]

Touhy Regulations

AGENCY: Millennium Challenge Corporation.

ACTION: Final rule.

SUMMARY: This rule implements the procedures by which the Millennium Challenge Corporation responds to subpoenas or other official demands for information and testimony served upon itself or its employees.

DATES: This rule is effective July 31, 2014.

FOR FURTHER INFORMATION CONTACT: John C. Mantini, Office of the General Counsel, Millennium Challenge Corporation, 202–521–3863, or *foia@mcc.gov*.

SUPPLEMENTARY INFORMATION: The United States Supreme Court held in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951), that the head of a federal agency may make the determination on his/her sole authority to produce documents and authorize employee’s testimony in response to a subpoena or other demand for information. This regulation governs the Millennium Challenge Corporation’s procedures for authorizing or denying such demands. MCC published a proposed regulation on May 9, 2014 in 79 FR 26659 and invited interested parties to submit comments. MCC received no comments. Accordingly, the proposed regulation is adopted as a final regulation with only minor editorial changes.

List of Subjects in 22 CFR Part 1305:

Administrative Practice and procedure, Courts, Disclosure, Exemptions, Government employees, Subpoenas, Records, Testimony.

■ For the reasons set forth above, the Millennium Challenge Corporation amends Chapter XIII of 22 CFR by adding Part 1305, to read as follows:

PART 1305—RELEASE OF OFFICIAL INFORMATION AND TESTIMONY BY MCC PERSONNEL AS WITNESSES

Sec.

- 1305.1 Purpose and scope.
- 1305.2 Definitions.
- 1305.3 Production prohibited unless approved.
- 1305.4 Factors to be considered by the General Counsel.
- 1305.5 Service of demands.
- 1305.6 Processing demands.
- 1305.7 Final determination.
- 1305.8 Restrictions that apply to testimony.
- 1305.9 Restrictions that apply to released documents.
- 1305.10 Procedure when a decision is not made prior to the time a response is required.
- 1305.11 Procedure in the event of an adverse ruling.
- 1305.12 No private right of action.

Authority: 5 U.S.C. 301.

§ 1305.1 Purpose and scope.

Pursuant to 5 U.S.C. 301, the head of an executive department or military department may prescribe regulations for the government of his/her department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. Section 301 does not authorize withholding information from the public or limiting the availability of records to the public. This part contains the regulations of the Millennium Challenge Corporation (MCC) concerning procedures to be followed when a request, subpoena, order or other demand (hereinafter in this part referred to as a “demand”) of a court or other authorities in any state or federal proceeding is issued for the production or disclosure of:

- (a) Any material contained in the files of MCC;
- (b) Any information relating to materials contained in the files of MCC; or
- (c) Any information or material acquired by an employee of MCC during the performance of the employee’s official duties or because of the employee’s official status.

§ 1305.2 Definitions.

For purposes of this part:

- (a) *Demand* means a request, order, or subpoena for testimony or documents related to or for possible use in a legal proceeding.
- (b) *Document* means any record or other property, no matter what media and including copies thereof, held by MCC, including without limitation, official letters, telegrams, memoranda, reports, studies, calendar and diary entries, maps, graphs, pamphlets, notes,

charts, tabulations, analyses, statistical or informational accumulations, any kind of summaries of meetings and conversations, film impressions, magnetic tapes and sound or mechanical reproductions.

(c) *Employee* means all employees and officers of MCC, including contractors who have been appointed by, or are subject to the supervision, jurisdiction or control of MCC. The procedures established within this part also apply to former employees and contractors of MCC.

(d) *General Counsel* means the General Counsel or MCC employee to whom the General Counsel has delegated authority to act under this subpart.

§ 1305.3 Production prohibited unless approved.

No employee or former employee shall, in response to a demand of a court or other authority, disclose any information relating to materials contained in the files of MCC, or disclose any information or produce any material acquired as part of the performance of the person’s official duties, or because of the person’s official status, without the prior, written approval of the General Counsel.

§ 1305.4 Factors to be considered by the General Counsel.

(a) In deciding whether to authorize the release of official information or the testimony of employees concerning official information, the General Counsel shall consider the following factors:

- (1) Whether the demand is unduly burdensome;
- (2) MCC’s ability to maintain impartiality in conducting its business;
- (3) Whether the time and money of the United States would be used for private purposes;
- (4) The extent to which the time of employees for conducting official business would be compromised;
- (5) Whether the public might misconstrue variances between personal opinions of employees and MCC policy;
- (6) Whether the demand demonstrates that the information requested is relevant and material to the action pending, genuinely necessary to the proceeding, unavailable from other sources, and reasonable in its scope;
- (7) Whether the number of similar demands would have a cumulative effect on the expenditure of agency resources;
- (8) Whether disclosure otherwise would be inappropriate under the circumstances; and
- (9) Any other factor that is appropriate.

(b) Among those demands in response to which compliance will not ordinarily be authorized are those with respect to which any of the following factors exists:

- (1) The disclosure would violate a statute, Executive order, or regulation;
- (2) The integrity of the administrative and deliberative processes of MCC would be compromised;
- (3) The disclosure would not be appropriate under the rules of procedure governing the case or matter in which the demand arose;
- (4) The disclosure, including release in camera, is not appropriate or necessary under the relevant substantive law concerning privilege;
- (5) The disclosure, except when in camera and necessary to assert a claim of privilege, would reveal information properly classified or other matters exempt from unrestricted disclosure; or
- (6) The disclosure would interfere with ongoing enforcement proceedings, compromise constitutional rights, reveal the identity of an intelligence source or confidential informant, or disclose trade secrets or similarly confidential commercial or financial information.

§ 1305.5 Service of demands.

Demands for official documents, information or testimony must be in writing, and served on the General Counsel, Millennium Challenge Corporation, 875 Fifteenth Street NW., Washington, DC 20005–2221.

§ 1305.6 Processing demands.

(a) After service of a demand to produce or disclose official documents and information, the General Counsel will review the demand and, in accordance with the provisions of this subpart, determine whether, or under what conditions, to authorize the employee to testify on matters relating to official information and/or produce official documents.

(b) If information or material is sought by a demand in any case or matter in which MCC is not a party, an affidavit or, if that is not feasible, a statement by the party seeking the information or material, or by his/her attorney setting forth a summary of the information or material sought and its relevance to the proceeding, must be submitted before a decision is made as to whether materials will be produced or permission to testify or otherwise provide information will be granted. Any authorization for testimony by a present or former employee of MCC shall be limited to the scope of the demand.

(c) When necessary, the General Counsel will coordinate with the Department of Justice to file appropriate

motions, including motions to remove the matter to Federal court, to quash, or to obtain a protective order.

(d) If a demand fails to follow the requirements of these regulations, MCC will not allow the testimony or produce the documents.

(e) MCC will process demands in the order in which they are received. Absent unusual circumstances, MCC will respond within 45 days of the date that the demand was received. The time for response will depend upon the scope of the demand.

(f) The General Counsel may grant a waiver of any procedure described by this subpart where a waiver is considered necessary to promote a significant interest of MCC or the United States or for other good cause.

§ 1305.7 Final determination.

The General Counsel makes the final determination on demands to employees for production of official documents and information or testimony. All final determinations are within the sole discretion of the General Counsel. The General Counsel will notify the requester and the Court or other authority of the final determination, the reasons for the grant or denial of the demand, and any conditions that the General Counsel may impose on the release of documents, or on the testimony of an employee. When in doubt about the propriety of granting or denying a demand for testimony or documents, the General Counsel should consult with the Department of Justice.

§ 1305.8 Restrictions that apply to testimony.

(a) The General Counsel may impose conditions or restrictions on the testimony of MCC employees including, for example, limiting the areas of testimony or requiring the requester and other parties to the legal proceeding to agree that the transcript of the testimony will be kept under seal or will only be used or made available in the particular legal proceeding for which testimony was requested. The General Counsel may also require a copy of the transcript of testimony at the requester's expense.

(b) MCC may offer the employee's declaration in lieu of testimony, in whatever form the court finds acceptable.

(c) If authorized to testify pursuant to this part, an employee may testify to relevant unclassified materials or information within his or her personal knowledge, but, unless specifically authorized to do so by the General Counsel, the employee shall not:

(1) Disclose confidential or privileged information; or

(2) For a current MCC employee, testify as an expert or opinion witness with regard to any matter arising out of the employee's official duties or the functions of MCC, unless testimony is being given on behalf of the United States.

§ 1305.9 Restrictions that apply to released documents.

(a) The General Counsel may impose conditions or restrictions on the release of official documents and information, including the requirement that parties to the proceeding obtain a protective order or execute a confidentiality agreement to limit access and any further disclosure. The terms of the protective order or of the confidentiality agreement must be acceptable to the General Counsel. In cases where protective orders or confidentiality agreements have already been executed, MCC may condition the release of official documents and information on an amendment to the existing protective order or confidentiality agreement.

(b) If the General Counsel so determines, original MCC documents may be presented in response to a demand, but they are not to be presented as evidence or otherwise used in a manner by which they could lose their identity as official MCC documents nor are they to be marked or altered. In lieu of original records, certified copies will be presented for evidentiary purposes. (See 28 U.S.C. 1733).

§ 1305.10 Procedure when a decision is not made prior to the time a response is required.

If a response to a demand is required before the General Counsel can make the determination referred to above, the General Counsel, when necessary, will provide the court or other competent authority with a copy of this part, inform the court or other competent authority that the demand is being reviewed, and respectfully seek a stay of the demand pending a final determination.

§ 1305.11 Procedure in the event of an adverse ruling.

If the court or other competent authority declines to stay the demand in response to a request made in accordance with § 1305.10, or if the court or other competent authority rules that the demand must be complied with irrespective of the instructions from the General Counsel not to produce the material or disclose the information sought, the employee or former employee upon whom the demand has been made shall respectfully decline to

comply with the demand (*United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951)).

§ 1305.12 No private right of action.

This part is intended only to provide guidance for the internal operations of MCC, and is not intended to, and does not, and may not be relied upon, to create a right or benefit, substantive or procedural, enforceable at law by a party against the United States.

Dated: July 11, 2014.

John Mantini,

Assistant General Counsel, Millennium Challenge Corporation.

[FR Doc. 2014-16757 Filed 7-30-14; 8:45 am]

BILLING CODE 9211-03-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9685]

RIN 1545-BM18

Segregation Rule Effective Date

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary regulations under section 382 of the Internal Revenue Code (Code) that modify the effective date provision of recently published regulations. These regulations affect corporations whose stock is or was acquired by the Department of the Treasury (Treasury) pursuant to certain programs under the Emergency Economic Stabilization Act of 2008 (EESA). The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**. This document also modifies the existing regulations to provide a cross-reference to this temporary regulation.

DATES: *Effective Date:* These regulations are effective on July 31, 2014.

Applicability Date: For dates of applicability, see section 1.382-3T(j)(17).

FOR FURTHER INFORMATION CONTACT: Stephen R. Cleary, (202) 317-5353 (not a toll-free number).

SUPPLEMENTARY INFORMATION: