or Principal Avionics Inspector, as appropriate, or lacking a principal inspector, your local Flight Standards District Office.

Related Information

(j) For more information about this AD, contact Georgios Roussos, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6482; fax (425) 917–6590.

(k) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; *e-mail me.boecom@boeing.com;* Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on December 10, 2010.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010–31828 Filed 12–17–10; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 240 and 249

[Release No. 34–63347; File No. S7–35–10]

RIN 3235–AK79

Security-Based Swap Data Repository Registration, Duties, and Core Principles

Correction

In proposed rule document 2010–29719 beginning on page 77306 in the issue of December 10, 2010, make the following corrections:

1. On page 77320, in the third column, footnote 74, in the fourth line, "recordkeeping" should read "record keeping".

2. On page 77321, in the second column, below the heading *Request for Comment,* in the fifth bulleted paragraph, in the tenth line, "requiring" should read "require".

3. On page 77324, in the third column, footnote 90, in the fifth line, "recordkeeping" should read "record keeping".

4. On page 77338, the last line of text in the third column, prior to footnote 164 on the page, should read "information maintained by the SDR,[165]".

5. On the same page, in the same column, after footnote 164, add footnote 165 to read as follows:

[165] *See* Public Law 111–203 (adding Exchange Act Section 12(n)(5)(D)(i)).

6. On page 77347, in the second column, in the tenth line from the bottom of the page, "conflict" should read "conflicts".

7. On page 77356, in the third column, in thirty-first line, "systematically" should read "systemically".

8. On the same page, in the same line of the same column, "Therefor" should read "Therefore".

§ 249.1500 [Corrected]

9. On page 77375, in § 249.1500, before the first line in the first column, insert the following text:

EXHIBITS—BUSINESS ORGANIZATION

13. List as Exhibit A any person as defined in Section 3(a)(9) of the

10. On the same page, in the second column, in the fifth, eleventh, and fifteenth lines from the bottom of the page, "l5" should read "15".

[FR Doc. C1–2010–29719 Filed 12–17–10; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 500

[Docket No. FDA–2010–N–0612]

Animal Drugs, Feeds, and Related Products; Regulation of Carcinogenic Compounds in Food-Producing Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding compounds of carcinogenic concern used in food-producing animals. Specifically, the Agency is clarifying the definition of "S_o" and revising the definition of "S_m" so that it conforms to the clarified definition of S_o. Other clarifying and conforming changes are also being made.

DATES: Submit either electronic or written comments on the proposed rule by March 7, 2011. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by January 19, 2011 (*see* the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0612, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (*see* the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, *see* the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kevin Greenlees, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6975. e-mail: *kevin.greenlees@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) contains three anticancer, or Delaney, clauses: Sections 409(c)(3)(A), 512(d)(1)(I), and 721(b)(5)(B)(i) (21 U.S.C. 348(c)(3)(A), 360b(d)(1)(I), and 379e(b)(5)(B)(i)), pertaining to food additives, new animal drugs, and color additives, respectively.

These clauses prohibit approval of substances that have been shown to induce cancer in man or animals. However, each clause contains an exception, termed the "Diethylstilbestrol (DES) Proviso," that permits administration of such substances to food-producing animals where: (1) The food additive, color additive, or new animal drug will not adversely affect the animal; and (2) no residue of the food additive, color additive, or new animal drug will be found in any edible portion of that animal by a method of examination prescribed or approved by the Secretary of Health and Human Services by regulation. The regulations under part 500 (21 CFR part 500), subpart E entitled "Regulation of Carcinogenic Compounds Used in Food-Producing Animals," implement the DES Proviso. To elaborate on how to determine that there is no residue, and thus demonstrate that the second prong of the DES Proviso has been satisfied, the regulations define several terms, including S_o and S_m.

S_o is currently defined as the concentration of the compound of carcinogenic concern in the total diet of test animals that corresponds to a maximum lifetime risk of cancer to the test animals of 1 in 1 million, and is calculated from tumor data of the cancer bioassays using a statistical extrapolation procedure. The definition of S_o also provides that FDA will assume that the S_o corresponds to the concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to people. The concentration, derived from the S_o, of residues of carcinogenic concern in a specific edible tissue is termed the S_m. Sponsors are required to submit to FDA a regulatory analytical method that is an aggregate of all experimental procedures for measuring and confirming the presence of the marker residue of the sponsored compound in the target tissue of the target animal. FDA can be assured that there is no residue of carcinogenic concern when no residue of the compound is detectable (that is, the marker residue is below the limit of detection) using the approved regulatory analytical method.[1] A marker residue is selected whose concentration is in a known relationship to the concentration of the residue of carcinogenic concern in the last tissue to deplete to its S_m. This tissue is known as the target tissue and the concentration of the marker residues is known as the R_m. The limit of detection of the approved regulatory analytical method must be capable of measuring the selected marker residue at the R_m in the selected target tissue. When residues of carcinogenic concern are below the R_m in the target tissue as measured by the approved regulatory analytical method, the residues of carcinogenic concern in target tissue and all other edible tissues are below their respective S_m and therefore consumption of tissues containing these residues would not exceed the S_o. The detection of the marker residue in the target tissue below the R_m by the approved regulatory analytical method can be taken as confirmation that the residue of carcinogenic concern does not exceed S_m in each of the edible tissues and, therefore, that the residue of carcinogenic concern in the diet of people does not exceed S_o. However, any detectable concentration of the marker residue by the approved regulatory analytical method, even if below the R_m, fails to satisfy the statutory requirements of the DES Proviso. The detection of any concentration would mean that the second prong of the DES Proviso has not been satisfied because it has not been shown that no residue of the substance is present in any edible portion of the animal at issue.

As described previously, the approach for evaluating compounds of carcinogenic concern currently set forth in § 500.84 utilizes a statistical extrapolation procedure that calculates a concentration of residue of carcinogenic concern that corresponds to a maximum lifetime risk to the test animal of 1 in 1 million. In addition, to provide flexibility, § 500.90 permits the use of alternative procedures to satisfy the DES Proviso, when the person requesting the use of alternative procedures clearly sets forth the reasons why the alternative procedures will provide a basis for concluding that approval of the compound satisfies the requirements of the Delaney Clause provisions of the FD&C Act, including the DES Proviso.

In recent years, FDA has, at times, been asked to consider allowing the use of alternative procedures to satisfy the DES Proviso. Some of these proposed alternative procedures did not rely on a statistical extrapolation of the data to a 1 in 1 million risk of cancer to test animals, but nevertheless the S_o, S_m, R_m, and regulatory analytical method resulting from these alternative approaches would be expected to ensure that consumption of food derived from animals treated with the carcinogenic new animal drug would result in no significant increase in the risk of cancer to people. In the course of considering these proposed alternative procedures, FDA has also considered whether the term S_o, as currently defined, adequately addresses concentrations of residues of carcinogenic concern in the total human diet that are found to represent no significant increase in the risk of cancer to people, but which are not derived from a statistical extrapolation of data to a 1 in 1 million risk of cancer to test animals.

The current definition in § 500.82 primarily defines S_o as the concentration of the compound of carcinogenic concern that corresponds to the 1 in 1 million lifetime risk of cancer to the test animals and secondarily as corresponding to the concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in a risk of cancer to people. Therefore, as presently constructed, the definition of S_o is not primarily defined as the concentration of residues of carcinogenic concern in the total human diet derived from procedures not involving the extrapolation of data to a 1 in 1 million risk of cancer to the test animals. Thus, were FDA to allow the use of alternative procedures that do not rely on a statistical extrapolation of the data to a 1 in 1 million risk of cancer to test animals to satisfy the DES Proviso, it would have to develop a new set of terminology to describe the Center for Veterinary Medicine's (CVM's) approach for evaluating these compounds of carcinogenic concern. The proposed changes to the definitions of S_o and S_m are intended to enable CVM to consider allowing the use of alternative procedures to satisfy the DES Proviso without requiring the development of a second, alternative, set of terminology.

FDA believes that a careful reading of the December 31, 1987, final rule (52 FR 49572 at 49586), suggests that an emphasis on no significant increase in the risk of cancer to the human consumer, rather than on the specific 1 in 1 million risk of cancer to the test animals approach, reflects the original intent of the regulation. (*See, e.g.,* 52 FR 49572 at 49575 and 49582.) FDA has concluded that the proposed redefinition of S_o is consistent with this original intent of the regulation.

For clarification purposes, FDA is also proposing a redefinition of S_m in § 500.82 to conform this definition with the redefinition of S_o as described previously. Specifically, S_m would mean the concentration of a residue of carcinogenic concern in a specific edible tissue corresponding to no

[1] The submission of such a method is approved as a collection of information under Office of Management and Budget (OMB) Control No. 0910–0032.

significant increase in the risk of cancer to the human consumer. However, the definition of S_m would also retain the existing reference to a maximum lifetime risk of cancer in the test animals of 1 in 1 million.

Finally, FDA is proposing to amend § 500.84(c) to clarify that for each compound that is regulated as a carcinogen, FDA will analyze the data submitted using either a statistical extrapolation procedure as provided in § 500.84(c)(1) or an alternate approach as provided in § 500.90.

FDA's goal in these changes is to clarify that the terms S_o and S_m apply even when the alternative procedures provided for in § 500.90 are used to satisfy the DES Proviso, not to alter the usual process for approving compounds of carcinogenic concern. As such, in the absence of a waiver of the requirements of § 500.84(c)(1), FDA maintains that sponsors must meet the conditions for approval set for in § 500.84, including the default approach of a 1 in 1 million lifetime risk to the test animal.

II. Legal Authority

This rule, if finalized, would amend part 500, subpart E in a manner consistent with the Agency's current understanding and application of these provisions. FDA was given authority in 21 U.S.C. 348, 360b, and 379e to establish methods of examination to determine that no residue of a food additive, new animal drug, or color additive of carcinogenic concern would be found in any edible portion of animals after slaughter or in any food yielded by or derived from living animals. Furthermore, FDA has the authority to take the actions proposed in this rule under various statutory provisions. These provisions include 21 U.S.C. 321, 331, 348, 360b, 371, and 379e.

III. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would not impose any direct or indirect costs on industry or government through the changes to the definitions of S_o and S_m and to § 500.84(c), but rather would clarify these definitions to enable FDA to consider using alternative procedures to satisfy the DES Proviso without requiring the development of a second, alternative, set of terminology, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

V. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 500.84 have been approved under OMB Control No. 0910–0032.

VII. Request for Comments

FDA requests comments to the proposed revisions to the definitions of S_m and S_o currently found in § 500.82(b) and to the proposed conforming changes to § 500.84(c). Specifically, the Agency requests that comments focus on the proposal to emphasize "no significant increase in the risk of cancer to the human consumer," rather than the more specific "1 in 1 million risk of cancer to the test animals" approach currently found in the definitions of S_m and S_o.

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Proposed Effective Date

The Agency is proposing that any final rule that may issue based upon this proposed rule become effective upon publication in the **Federal Register**.

List of Subjects in 21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCB's).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 500 be amended as follows:

PART 500—GENERAL

1. The authority citation for 21 CFR part 500 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

2. Revise the definitions of "S_m" and "S_o" in paragraph (b) of § 500.82 to read as follows:

§ 500.82 Definitions.

* * * * *

(b) * * *

S_m means the concentration of a residue of carcinogenic concern in a specific edible tissue corresponding to no significant increase in the risk of

cancer to the human consumer. For the purpose of § 500.84(c)(1), FDA will assume that this S_m will correspond to the concentration of residue in a specific edible tissue that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million.

S_o means the concentration of a residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to the human consumer. For the purpose of § 500.84(c)(1), FDA will assume that this S_o will correspond to the concentration of test compound in the total diet of test animals that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million.

* * * * *

3. Revise the introductory text of paragraph (c) of § 500.84 to read as follows:

§ 500.84 Conditions for approval of the sponsored compound.

* * * * *

(c) For each sponsored compound that FDA decides should be regulated as a carcinogen, FDA will either analyze the data from the bioassays using a statistical extrapolation procedure as outlined in paragraph (c)(1) of this section or evaluate an alternate procedure proposed by the sponsor as provided in § 500.90. In either case, paragraphs (c)(2) and (c)(3) of this section apply.

* * * * *

Dated: December 15, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31887 Filed 12–17–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 63

RIN 2900–AN73

Health Care for Homeless Veterans Program

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish regulations for contracting with community-based treatment facilities in the Health Care for Homeless Veterans (HCHV) program of the Department of Veterans Affairs (VA). It would formalize VA's policies and procedures in connection with this program, which is designed to assist certain homeless veterans in obtaining treatment from non-VA community-based providers. It would also clarify that veterans with substance use disorders may qualify for the program.

DATES: Comments on the proposed rule, including comments on the information collection provisions, must be received on or before February 18, 2011.

ADDRESSES: Written comments may be submitted through *http://www.Regulations.gov;* by mail or hand delivery to the Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; or by fax to 202–273–9026. Comments should indicate that they are submitted in response to "RIN 2900–AN73, Health Care for Homeless Veterans Program." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 (this is not a toll-free number) for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Robert Hallett, Healthcare for Homeless Veterans Manager, c/o Bedford VA Medical Center, 200 Springs Road, Bldg. 12, Bedford, MA 01730; (781) 687–3187 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: The HCHV program is authorized by 38 U.S.C. 2031, under which VA may provide outreach as well as "care, treatment, and rehabilitative services (directly or by contract in community-based treatment facilities, including halfway houses)" to "veterans suffering from serious mental illness, including veterans who are homeless." One of VA's national priorities is a renewed effort to end homelessness for veterans. For this reason, we are proposing to establish regulations that are consistent with the current administration of this program.

The primary mission of the HCHV program is to use outreach efforts to contact and engage veterans who are homeless and suffering from serious mental illness or a substance use disorder. Many of the veterans for whom the HCHV program is designed have not previously used VA medical services or been enrolled in the VA health care system.

Through the HCHV program, VA identifies homeless veterans with serious mental illness and/or substance use disorder, usually through medical intervention, and offers community-based care to those whose conditions are determined, clinically, to be managed sufficiently that the individuals can participate in such care. We have assisted homeless veterans with substance use disorders through this program because, based on our practical understanding and experience, the vast majority of homeless veterans have substance use disorders. Treating substance use as a mental disorder is consistent with the generally accepted "disease model" of alcoholism and drug addiction treatment, as well as the modern use of medical intervention to treat the condition. We believe that if a substance use disorder is a contributing cause of homelessness, then that disorder is serious; therefore, it is consistent to include such veterans in a program designed for "veterans suffering from serious mental illness, including veterans who are homeless." 38 U.S.C. 2031(a).

Veterans who are identified and who choose to participate in this form of care as part of their treatment plan are then referred by VA to an appropriate non-VA community-based provider. In some cases, VA will continue to actively medically manage the veteran's condition, while in other cases a VA clinician may determine that a veteran can be sufficiently managed through utilization of non-medical resources, such as 12-step programs.

To provide the community-based care, VA contracts, via the HCHV program, with non-VA community-based providers, such as halfway houses, to provide to these veterans housing and mental health and/or substance use disorder treatment. VA provides per diem payments to these non-VA community-based providers for the services provided to veterans. Service provision within these contracts is typically short-term, because during their stay veteran-participants are connected with other resources designed to provide longer-term housing. These contracts, and the per diem payment, are governed by the Federal Acquisition Regulations, and the VA supplements thereto contained in the Veterans Affairs Acquisition Regulations at chapter 8 of title 48, CFR. These are the rules that specifically govern requirements exclusive to VA contracting actions.

We propose to establish a new 38 CFR part 63 for the HCHV program because the program is unique and the proposed rule would not apply to therapeutic housing or other VA programs designed to end homelessness. The primary purposes of this rulemaking are to establish eligibility criteria for veterans