DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0052]

Documenting Electronic Data Files and Statistical Analysis Programs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft revised guidance for industry (GFI) #197 entitled ''Documenting Electronic Data Files and Statistical Analysis Programs.'' This draft revised guidance is provided to inform sponsors of recommendations for documenting electronic data files and statistical analyses submitted to the Center for Veterinary Medicine (CVM) to support new animal drug applications.

DATES: Submit either electronic or written comments on the draft revised guidance by July 20, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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 as follows:

- *Mail/Hand delivery/Courier (for written/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–2009–D–0052 for ''Documenting Electronic Data Files and Statistical Analysis Programs.'' 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 the electronic and written/paper 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Virginia Recta, Center for Veterinary Medicine (HFV–160), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0840, *virginia.recta@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft revised GFI #197 entitled ''Documenting Electronic Data Files and Statistical Analysis Programs.'' This draft revised guidance is provided to inform sponsors of recommendations for documenting electronic data files and statistical analyses submitted to CVM to support new animal drug applications. These recommendations are intended to reduce the number of revisions that may be required for CVM to effectively review data submissions and to simplify submission preparation by providing a recommended documentation framework.

II. Significance of Guidance

This level 1 draft revised guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Documenting Electronic Data Files and Statistical Analysis Programs.'' 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 not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: May 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10722 Filed 5–18–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0361]

Mary C. Holloway; Order Revoking a Proposed Order of Debarment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking a proposed order, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), to debar Mary C. Holloway (Holloway) for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. Holloway, through counsel, filed a request for a hearing, as well as information and analysis in support of that request, in response to the proposed debarment order. FDA has determined that pursuing debarment of Holloway is no longer appropriate.

DATES: This order is applicable May 21, 2018.

FOR FURTHER INFORMATION CONTACT: Nathan Sabel, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 301–796–8588.

SUPPLEMENTARY INFORMATION:

I. Background

On April 8, 2009, Holloway, formerly a regional sales manager at Pharmacia & Upjohn Company, Inc. (Pharmacia), pled guilty to a Federal misdemeanor offense under sections 301(a), 303(a)(1), and 502(f) of the FD&C Act (21 U.S.C. 331(a), 333(a)(1), and 352(f)). In June 2009, the U. S. District Court for the District of Massachusetts entered the conviction and sentenced Holloway to probation. The basis for the conviction was Holloway's involvement in Pharmacia's introduction into interstate commerce of its drug BEXTRA, a pain reliever and anti-inflammatory, for the unapproved use of treating pre- and postoperative surgical pain. Before it was removed from the market several years later, BEXTRA was only approved for treatment of arthritis and primary dysmenorrhea. In September 2009, Pharmacia pled guilty to a felony violation of the FD&C Act for the promotion of BEXTRA and other drugs for unapproved uses.

By letter dated January 20, 2010, FDA's Office of Regulatory Affairs (ORA) notified Holloway of a proposal to debar her for 5 years from providing services in any capacity to a person having an approved or pending drug product application. The proposal stated that Holloway is subject to permissive debarment based on a finding, under section 306(b)(2)(B)(i) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)), that she was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product and that the type of conduct serving as the basis for the conviction undermines the process for the regulation of drugs. The proposal further concluded that Holloway should be debarred for the maximum period of 5 years under section 306(c)(2)(A)(iii) of the FD&C Act based on four applicable considerations in section 306(c)(3).

In a letter dated February 18, 2010, through counsel, Holloway requested a hearing on the proposal. On March 24, 2010, Holloway submitted materials and arguments in support of her request. In her submissions, Holloway acknowledged her conviction of a misdemeanor under Federal law. Holloway conceded that she is subject to debarment as a result of this conviction, but she argues nonetheless that she is entitled to a hearing to determine whether permissive debarment is appropriate. Specifically, Holloway argued that, with respect to the considerations for determining the appropriateness and period of debarment under section 306(c)(3) of the FD&C Act, there are genuine and substantial issues of fact for resolution at a hearing.

By letter dated April 3, 2013, the Office of the Commissioner, in order to determine whether granting a hearing would be appropriate, requested that ORA submit a response to Holloway's request for a hearing. ORA was invited to include any documentary evidence, information, or analysis that it deemed appropriate in support of its response. Holloway was afforded an opportunity to submit evidence and arguments in opposition. ORA submitted its response on August 30, 2013. Holloway, through counsel, replied to ORA's response on November 15, 2013.

Under § 12.26 (21 CFR 12.26), if FDA determines upon review of a request for hearing that the order at issue should be modified or revoked, FDA may modify or revoke the order by notice in the **Federal Register**. Based upon a review of the record, the Acting Chief Scientist concludes that it is appropriate under § 12.26, in this instance, to revoke the proposed order to debar Holloway for 5 years.

II. Arguments

In the proposal to debar Holloway for 5 years, ORA noted that there are four applicable considerations for determining the appropriateness and period of Holloway's debarment under section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of her offense under section 306(c)(3)(A); (2) the nature and extent of management participation in the offense under section 306(c)(3)(B); (3) the nature and extent of voluntary steps taken to mitigate the impact on the public under section 306(c)(3)(C); and (4) prior convictions involving matters within the jurisdiction of FDA under section 306(c)(3)(F). ORA found that the first three of those considerations weigh in favor of debarment and noted, as to the fourth consideration, that FDA is unaware of any prior convictions. In finding that the each of the first three considerations weighs in favor of debarment, ORA appears to have characterized Holloway's conduct based on contested allegations from Holloway's criminal proceedings.

Holloway challenged both ORA's conclusions with respect to all three considerations in dispute and the factual underpinnings of those conclusions. Holloway contended that, under section 306(i) of the FD&C Act, FDA may not take any action under sections 306(b) or section 306(c) with respect to any person ''unless [FDA] has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact.'' Section 306(c)(3) explicitly requires that FDA consider, ''where applicable,'' certain factors ''[i]n determining the appropriateness and the period of debarment'' for any permissive debarment.

In proposing to debar Holloway for 5 years, ORA appears to have based its findings with respect to certain considerations in section 306(c)(3) of the FD&C Act largely on the factual