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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*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

BILLING CODE 4164–01–P

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

allegations in the criminal information to which Holloway pled guilty under her plea agreement. As Holloway argues, however, the records of her criminal proceedings reflect that she did not admit to any of the specific factual allegations in the information during the plea colloquy conducted by the court. In fact, her attorney during the criminal proceedings explicitly stated, ''[The information] contains many allegations that Ms. Holloway disputes.'' After the prosecution summarized the evidence that it planned to introduce at trial, which closely mirrored the allegations in the information, the court accepted Holloway's guilty plea on the basis of the following exchange:

THE COURT: Okay. I gather that some of the facts are in dispute; is that correct?

THE DEFENDANT: Correct.

THE COURT: Do you want to make a statement or, counsel, do you want to make a statement?

* * * * *

[DEFENSE COUNSEL]: Ms. Holloway is, she is prepared to admit that she promoted BEXTRA for off label usage, and she understands that that constitutes the introduction of BEXTRA into interstate commerce with inadequate directions for use.

THE COURT: All right. Ms. Holloway, do you agree, do you accept your counsel's representation as to the facts that you accept to be true?

THE DEFENDANT: Yes, ma'am.

In her request for a hearing and subsequent submissions (March 24, 2010, and November 15, 2013), Holloway argued that her lack of admission to any specific facts during her criminal proceedings calls into question ORA's findings with respect to certain considerations under section 306(c)(3). In addition, with regard to certain ORA allegations in the proposed order to debar Holloway (January 20, 2010), and in support of facts weighing against debarment, Holloway has presented particularized challenges supported by explanations or documentary evidence.

After a review of the record, the Acting Chief Scientist concludes that, given the exceptional circumstances of this matter, it appears that it would likely be necessary to grant the pending request for a hearing. Such a hearing would require a broad scope to address any genuine and substantial issues of fact that are material to weighing the applicable considerations under section 306(c)(3) of the FD&C Act. As a result of this extraordinary posture, the scope of the disputed facts in this matter includes many of the facts that a prior criminal proceeding would typically have established, as well as those additional facts in dispute that relate to certain of the applicable debarment considerations in section 306(c)(3) of the FD&C Act. Because few factual findings relating to Holloway's specific conduct and actions between December 2001 and April 2005 underlying her 2009 conviction were generated during the criminal proceedings, a hearing to establish ORA's proposed findings would require a substantial devotion of the Agency's limited resources to this individual debarment proceeding.

The Acting Chief Scientist has weighed the Agency's limited resources against the factors that weigh in favor of proceeding to evaluate ORA's proposed debarment order at an evidentiary hearing. Chief among these countervailing considerations are the nature and seriousness of the offense articulated by ORA and the Agency's interest in effectuating the remedial purpose of the statute in furtherance of the public health. The Acting Chief Scientist has accorded significant weight to those countervailing considerations but, in reaching a decision in this matter, has balanced those considerations against the extraordinary resources necessary to conduct an evidentiary hearing on the factual underpinnings for ORA's proposed findings as to the considerations in section 306(c)(3) of the FD&C Act, when there were few specific facts established as part of the criminal proceeding.

After a careful evaluation of the arguments and information provided by both ORA and Holloway as they relate to the nature and breadth of the factual disputes at issue here, and after a consideration of the resources necessary to proceed under this unusual set of circumstances, the Acting Chief Scientist has determined that the revocation of the proposed order to debar Holloway is appropriate in this instance.

III. Order

Upon review of the request for hearing, evidence, and arguments, the Acting Chief Scientist revokes the January 20, 2010, proposed order to debar Holloway and provides this notice of revocation in the **Federal Register** as required by § 12.26.

Dated: May 14, 2018.

Denise Hinton,

Acting Chief Scientist.

[FR Doc. 2018–10685 Filed 5–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recruitment of Sites for Assignment of National Health Service Corps Scholarship Program Participants

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces that the listing of entities that will receive priority for assignments of National Health Service Corps (NHSC) Scholarship recipients (NHSC scholars) was posted on the Health Workforce Connector website (formerly known as the NHSC Jobs Center) at *https://connector.hrsa.gov/.* The Health Workforce Connector includes sites approved to receive an assignment of NHSC scholars who are available for service during the period of October 1, 2018, through September 30, 2019, as well as the site's Health Professional Shortage Area (HPSA) scores. Please note that entities on this list may or may not have current job vacancies.

DATES: Entities interested in providing additional data and information in support of their inclusion on the proposed listing, or in support of a higher priority determination, must do so in writing no later than June 20, 2018.

ADDRESSES: Entities wishing to submit information to support an entity's inclusion on the list or to request a higher priority determination should submit it to Beth Dillon, Director, Division of Regional Operations, Bureau of Health Workforce, 1961 Stout Street, Denver, CO 80294. HRSA will consider this information when preparing the final list of entities that receive priority for the assignment of NHSC scholars.

SUPPLEMENTARY INFORMATION: The program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

Evaluation and Selection Process

In approving applications for the assignment of NHSC scholars, the HHS Secretary shall give priority to any such application that is made for a position in a HPSA with the greatest shortage. HPSAs of greatest shortage are defined by its HPSA scores.

For the program year October 1, 2018, through September 30, 2019, priority for assignment of NHSC scholars will be