Dated: August 20, 2008.

Mary M. McGeein,

Principal Deputy Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–N–0166] (formerly Docket No. 2006N–0238)

Maria Anne Kirkman Campbell; Denial of Hearing; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Dr. Maria Anne Kirkman Campbell (Dr. Campbell) from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Campbell was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, and conduct otherwise relating to the regulation of a drug product under the act. Dr. Campbell failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action. Even assuming that any statement in Dr. Campbell's correspondence with FDA were to be construed as requesting a hearing, Dr. Campbell has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action. Therefore, we are, in the alternative, issuing an order denying any such assumed request for a hearing because we find that there is no genuine and substantial issue of fact to grant a hearing on the debarment, if a hearing were requested.

DATES: This order is effective September 2, 2008.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian Pendleton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6304, Silver Spring, MD, 20993–0002, 301–796–3504.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Section 306(a)(2)(B) of the act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

On March 25, 2004, the U.S. District Court for the Northern District of Alabama accepted Dr. Campbell's plea of guilty and convicted her of one count of mail fraud, a felony under 18 U.S.C. 1341 and 2. Specifically, Dr. Campbell admitted to submitting a fraudulent case report form (reflecting enrollment of a nonexistent person) while serving as a clinical investigator in a clinical study designed to test the safety and effectiveness of an antibacterial drug product, Ketek (telithromycin), for the treatment of respiratory tract infections. The clinical study was to be submitted to FDA in support of approval of Ketek.

Accordingly, in a letter dated February 28, 2007, and hand delivered on March 5, 2007, FDA served Dr. Campbell a notice proposing to permanently debar her from providing services in any capacity to a person having an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) and (a)(2)(B) of the act, that Dr. Campbell was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, and conduct otherwise relating to the regulation of a drug product. The letter offered Dr. Campbell an opportunity to request a hearing on the proposal, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action.

The letter also informed Dr. Campbell that her request for a hearing could not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact requiring a hearing. In addition, the letter informed Dr. Campbell that the only material issue of fact was whether she was convicted as alleged in the letter, and that the facts underlying her conviction are not at issue in this proceeding. The letter also informed Dr. Campbell that if it conclusively appeared from the face of the information and factual analyses in her request for a hearing that there was no genuine and substantial issue of fact that precluded the order of debarment, we would deny her request for a hearing and enter a final order of debarment. Finally, the letter informed Dr. Campbell that if she were to file a request for a hearing, she was required to file, on or before 60 days from the date of receipt of the letter, the information on which she relied to justify a hearing.

Dr. Campbell has responded to the proposal to debar her but has not requested a hearing.[1] Her failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment.

Even assuming that any statement in Dr. Campbell's correspondence with FDA were to be construed as requesting a hearing, Dr. Campbell has not submitted information that would justify granting a hearing. Therefore, we are, in the alternative, hereby denying any such assumed request for a hearing because Dr. Campbell has failed to show that there is a genuine and substantial issue of fact requiring a hearing. Dr. Campbell has not offered any information or factual analyses to refute that she was convicted of mail fraud for conduct relating to the development or approval of a drug product, or otherwise relating to the regulation of a drug product under the act.

II. Findings and Order

Therefore, the Associate Commissioner for Regulatory Affairs, under section 306(a)(2)(A) and (a)(2)(B) of the act and under authority delegated to her, finds that Dr. Maria Anne Kirkman Campbell has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for

[1]After we served Dr. Campbell on March 5, 2007, with notice of the agency's proposal to debar her, Dr. Campbell sent a series of letters to the agency—dated March 9, 2007, April 6, 2007, May 23, 2007, July 17, 2007, August 21, 2007, and January 13, 2008,—and participated in a teleconference with FDA on April 9, 2007. Although some of Dr. Campbell's correspondence refers to another proceeding the agency initiated against Dr. Campbell (investigator disqualification under 21 CFR 312.70), instead of, or in addition to, the proposal to debar her, for the purposes of this order, we have taken into account all of Dr. Campbell's correspondence with the agency after March 5, 2007, as well as the transcript from the April 9, 2007, teleconference.

development or approval, of a drug product, and conduct otherwise relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Dr. Maria Anne Kirkman Campbell is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective as stated in the **DATES** section of this document (see section 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Dr. Campbell in any capacity, during her period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Campbell, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug application submitted by or with the assistance of Dr. Campbell during her period of debarment (section 306(c)(1)(B) of the act).

Any application by Dr. Campbell for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA–2006–N–0166 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20295 Filed 8–29–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0455]

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments and scientific data and information that may assist the agency to improve the guidance to industry set forth in the ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' issued in 1998. Specifically, FDA is seeking information about current agricultural practices and conditions used to grow, harvest, pack, cool, and transport fresh produce; risk factors for contamination of fresh produce associated with these practices; and possible measures that FDA could implement that would enhance the safety of fresh produce.

DATES: Submit written comments and scientific data and information or electronic comments by December 31, 2008.

ADDRESSES: Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments and scientific data and information to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2024.

SUPPLEMENTARY INFORMATION:

I. Background

A. Food Safety and Fresh Produce

FDA is responsible for ensuring the safety of all domestic and imported fresh fruits and vegetables consumed in the United States. Fresh fruits and vegetables are those that are likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form. Fresh fruits and vegetables may be intact and whole, such as whole apples, or cut in the act of harvest, such as heads of lettuce and bunches of broccoli.

Because most fresh produce is grown in a natural environment, it is vulnerable to contamination with pathogens (i.e., bacteria or other organisms that can cause disease). Factors that may affect the occurrence of such contamination include agricultural and/or post-harvest water quality, the use of manure as fertilizer, the presence of wild or domestic animals in or near fields or packing areas, worker health and hygiene, environmental conditions, production activities, and equipment and facility sanitation. Consequently, the manner in which fresh produce is grown, harvested, packed, cooled, and transported is crucial to minimizing the risk of microbial contamination. (We use the term ''microbial contamination'' to refer to contamination with any microorganism.)

Data reported to the U.S. Centers for Disease Control and Prevention (CDC) indicate that between 1973 and 1997 reported outbreaks of foodborne illness in the United States associated with fresh produce increased in absolute numbers and as a proportion of all reported foodborne outbreaks (Ref. 1). (By ''outbreak,'' we mean the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.) Unpublished data compiled by FDA indicate that from 1996 to 2007 there were approximately 72 reported outbreaks of foodborne illness associated with approximately 20 fresh produce commodities. Of this total, 13 outbreaks were associated with tomatoes, 11 outbreaks were associated with melons, and 24 outbreaks were associated with leafy greens such as lettuce and spinach (Ref. 2). These outbreaks involved a number of pathogens, including *Escherichia coli* (*E. coli*) O157:H7 and *Salmonella* species, and involved both domestic and imported produce. These totals include only those outbreaks in which our investigation has indicated that the contamination of the produce was not a result of exposure to an infected food handler or other unsafe food handling practice at the place of preparation and consumption (i.e., home or restaurant). There have also been a number of reported outbreaks associated with fresh produce in 2008.

B. FDA's GAPs/GMPs Guide

FDA places a high priority on identifying and promoting measures that can reduce the incidence of foodborne illness associated with fresh produce. In 1998, FDA and the U.S. Department of Agriculture issued