

providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. FDA bases this order on a finding that Mr. Kindness 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 under the act. After being given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Mr. Kindness failed to request a hearing. Mr. Kindness's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective November 24, 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: Jennifer J. Ross, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0372.

SUPPLEMENTARY INFORMATION:

I. Background

On September 28, 2006, the U.S. District Court for the Western District of Tennessee accepted George Kindness's guilty plea to one count of being aided and abetted in the introduction and delivery for introduction into interstate commerce of a misbranded drug with intent to defraud and mislead, a Federal felony offense under sections 301(a) and 303(a)(2) of the act (21 U.S.C. 331(a) and 333(a)(2)) and 18 U.S.C. 2. This offense was committed when Mr. Kindness, president, part-owner and laboratory director of Amcscot Medical Labs, Inc., manufactured and shipped a new drug for use in human beings for the treatment of cancer, without an investigational new drug application in effect.

As a result of this conviction, FDA sent Mr. Kindness by certified mail on September 7, 2007, a notice proposing to permanently debar Mr. Kindness from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. The proposal also offered Mr. Kindness an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(A) and (c)(2)(A)(ii) of the act

(21 U.S.C. 335a(a)(2)(A) and (c)(2)(A)(ii)), that Mr. Kindness 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. Mr. Kindness was provided 30 days to file objections and request a hearing. Mr. Kindness did not request a hearing. Mr. Kindness's failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director of the Center for Biologics Evaluation and Research, under section 306(a)(2)(A) of the act, and under authority delegated to the Director (FDA Staff Manual Guide 1410.35), finds that Mr. Kindness 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 a drug product.

As a result of the foregoing finding, Mr. Kindness is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application (section 306(c)(1)(B) of the act). A drug product means a drug, including a biological product, subject to regulation 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). Any person with an approved or pending drug product application including, but not limited to, a biologics license application, who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Kindness, in any capacity, during Mr. Kindness's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Kindness, during his permanent debarment, provides services in any capacity to a person with an approved or pending drug product application including, but not limited to, a biologics license application, Mr. Kindness will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated drug applications submitted by or with the assistance of Mr. Kindness during Mr. Kindness's permanent debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Kindness for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA-2007-N-0474 (formerly Docket No. 2007N-0292) and sent to the Division of Dockets

Management (see **ADDRESSES**). All such submissions are to be filed in four copies (§ 10.20(a) (21 CFR 10.20(a))). The public availability of information in these submissions is governed by § 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 (§ 10.20(j)(1)).

Dated: November 12, 2008.

Jesse Goodman,

Director, Center for Biologics Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-N-0488] (formerly Docket No. 2007N-0291)

Roy Page, M.D.; 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. Roy Page from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. FDA bases this order on a finding that Dr. Page 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 under the act. After being given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Dr. Page failed to request a hearing. Dr. Page's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective November 24, 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: Jennifer J. Ross, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0372.

SUPPLEMENTARY INFORMATION:**I. Background**

On August 4, 2005, the U.S. District Court for the Western District of Tennessee accepted Dr. Roy Page's guilty plea to one count of introduction and delivery for introduction into interstate commerce of a misbranded drug with the intent to mislead the FDA, a Federal felony offense under sections 301(a) and 303(a)(2) of the act (21 U.S.C. 331(a) and 333(a)(2)). This offense was committed when Dr. Page shipped tumor tissue and blood samples to Amescot Medical Laboratories, Inc., for manufacture of a new drug for the treatment of cancer in human beings without an investigational new drug application in effect.

As a result of this conviction, FDA sent Dr. Page by certified mail on September 7, 2007, a notice proposing to permanently debar Dr. Page from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. The proposal also offered Dr. Page an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(A) and (c)(2)(A)(ii) of the act (21 U.S.C. 335a(a)(2)(A) and (c)(2)(A)(ii)), that Dr. Page 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. Dr. Page was provided 30 days to file objections and request a hearing. Dr. Page did not request a hearing. Dr. Page's failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director of the Center for Biologics Evaluation and Research, under section 306(a)(2)(A) of the act, and under authority delegated to the Director (FDA Staff Manual Guide 1410.35), finds that Dr. Page 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 a drug product.

As a result of the foregoing finding, Dr. Page is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application (section 306(c)(1)(B) of the act). A drug product means a drug, including a biological product, subject to regulation 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). Any person with an approved or pending drug product application including, but not limited to, a biologics license application, who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Page, in any capacity, during Dr. Page's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Page, during his permanent debarment, provides services in any capacity to a person with an approved or pending drug product application including, but not limited to, a biologics license application, Dr. Page will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated drug applications submitted by or with the assistance of Dr. Page during Dr. Page's permanent debarment (section 306(c)(1)(B) of the act).

Any application by Dr. Page for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA-2007-N-0488 (formerly Docket No. 2007N-0291) and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies (§ 10.20(a) (21 CFR 10.20(a))). The public availability of information in these submissions is governed by § 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 (§ 10.20(j)(1)).

Dated: November 12, 2008.

Jesse Goodman,

Director, Center for Biologics Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2008-D-0592]

Draft Guidance for Industry on the Contents of a Complete Submission for the Evaluation of Proprietary Names; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Contents of a Complete Submission for the Evaluation

of Proprietary Names." This draft guidance provides recommendations to industry regarding the submission of a complete package that FDA intends to use to assess the safety of proposed proprietary drug and biological product names and other factors that, in association with the name, can contribute to medication errors. In addition, FDA intends to use this information in the assessment of promotional aspects of proposed proprietary names.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 23, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Carol Holquist, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4416, Silver Spring, MD 20993-0002, 301-796-2360, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Contents of a Complete Submission for