

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.

[FR Doc. E8-27803 Filed 11-21-08; 8:45 am]

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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

the Evaluation of Proprietary Names.” In performance goals agreed to under the September 27, 2007, reauthorization of the Prescription Drug User Fee Act (PDUFA IV), FDA agreed to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs. Among these measures, FDA agreed to publish guidance on the contents of a complete submission package for a proposed proprietary name for a drug/biological product. FDA also agreed to performance goals for review of proprietary names submitted during the investigational new drug application (IND) phase or with a new drug application (NDA) or biologics license application (BLA); the goals stipulate that a complete submission is required to begin the review clock. (See section IX.A at <http://www.fda.gov/oc/pdufa4/pdufa4goals.html>).

This draft guidance, when finalized, is intended to promote prevention of medication errors by assisting industry in the submission of complete product information that will help FDA to evaluate the safety of proposed proprietary drug and biological product names, taking into account 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.

This draft guidance applies to prescription drug products, including biologics, that are the subject of an IND, NDA, or abbreviated new drug application (ANDA); nonprescription drug products that are the subject of an NDA or ANDA; and biological products that are the subject of a BLA.

The draft guidance does not address other performance goals under PDUFA IV, including developing FDA internal policies and procedures to ensure that proprietary name review goals are met; developing guidance on best practices for naming, labeling, and packaging drugs and biologics to reduce medication errors; guidance on proprietary name evaluation best practices; and developing and implementing a pilot program for evaluating proposed proprietary names.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the contents of a complete submission for the evaluation of proprietary names. It does not create or

confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Paperwork Reduction Act of 1995

This draft 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 312 and FDA Form 1571 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 and FDA Form 356h have been approved under OMB control number 0910–0338.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.regulations.gov>.

Dated: November 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605–56606 as amended November 6, 1995; and as amended at 61 FR 65063, December 10, 1996; and last amended at 72 FR 33099, June 11, 2008.)

This notice reflects organizational changes in the Health Resources and Services Administration, Office of Rural Health Policy (RH). Specifically, this notice updates the functional statement of the Office of the Associate Administrator (RH), and creates the following components: Hospital-State Division (RH1), Community-Based Division (RH2), and the Border Health Division (RH3).

Chapter RH, Office of Rural Health Policy

Section RH, 00 Mission

Delete in its entirety and replace with the following:

The Office of Rural Health Policy serves as a focal point within the Department and as a principal source of advice to the Administrator and Secretary for coordinating efforts to strengthen and improve the delivery of health services to populations in the Nation's rural areas and border areas, providing leadership and interacting with stakeholders in the delivery of health care to underserved and at risk populations.

Section RH–10, Organization

Delete in its entirety and replace with the following:

The Office of Rural Health Policy (RH) is headed by the Associate Administrator who reports directly to the Administrator, Health Resources and Services Administration. The Office of Rural Health Policy includes the following components:

- (1) Office of the Associate Administrator (RH);
 - (2) Hospital State Division (RH1);
 - (3) Community Based Division (RH2);
- and
- (4) Border Health Division (RH3).

Section RH–20, Functions

Delete the functional statement for the Office of the Associate Administrator (RH) and replace in its entirety.