

Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the act.

FDA regulations require that an advertisement that makes claims about a prescription drug include a "air balance" of information about the benefits and risks of the advertised product, in terms of both content and presentation (21 CFR 202.1(e)(5)(ii)). In past research, FDA has focused primarily on the risk component of the risk/benefit ratio. In the interest of thoroughly exploring the issue of fair balance, however, the presentation of effectiveness, or benefit, information is equally important. This component has received less scrutiny. The proposed information collection described here is the first step in a three-phase study designed to investigate the role of effectiveness information in prescription drug print advertising. Along the way, we plan to investigate how health care providers use labeling and other materials and experiences to reach conclusions about drug effectiveness. We will use this information to provide a benchmark with which to compare the information consumers receive from direct-to-consumer advertisements.

The information collection described here refers only to the qualitative portion of the study series, Phase I. The purpose of the proposed information collection is twofold. First, we plan to

gather information in this phase that will help us to determine the proper concepts about which to inquire and the proper language to use when asking health care providers in the second phase about the effectiveness of certain drug products. Second, we will use the information gathered in this phase to identify gaps in the communication of effectiveness information in FDA sponsored materials, such as the physician labeling.

The proposed information collection described here (Phase I of a multi-phase project) will use "mental modeling," a qualitative research method that compares a model of the decisionmaking processes of a group or groups to a model of the same decisionmaking processes developed from expert knowledge and experience. In this study, the decision models of certain health care providers concerning effectiveness decisions of various treatment options for individuals suffering from insomnia or rheumatoid arthritis will be compared to a decision model concerning drug effectiveness that was derived from the knowledge and experience of FDA reviewers responsible for product labeling, National Institutes of Health clinical experts in this field, and others involved in the training of medical professionals. FDA will use telephone interviews to determine from the health care providers the factors that shape their understanding and decisions about the effectiveness of various drug treatments for their patients. A comparison

between expert and health care provider models based on the collected information may identify consequential knowledge gaps that can be redressed through messages designed by FDA and will provide information for designing the second (quantitative) phase of research with a national sample of health care providers.

Using a protocol derived from the research that resulted in the expert model, trained interviewers will conduct one-on-one telephone discussions with about 20 members of 2 categories of health care providers, general practitioners and rheumatologists, who provide direct patient care at least 50 percent of the time.

FDA has selected these two groups of physicians because the first group is reasonably likely to treat insomnia, whereas the second group treats rheumatoid arthritis. We selected these two medical conditions for focus in the next two phases of the research because prescription drug treatments for both are heavily advertised to consumers, drugs for these conditions are variable in their risk/benefit profiles, and yet they are each fairly complex in terms of risk/benefit profiles. Another function of the current information collection is to determine the feasibility of using these two medical conditions in the following quantitative phases.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours Per Response | Total Hours |
|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 40 | 1 | 1 | 0.75 | 30.0 |
| Total | | | | 30.0 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The study will involve about 40 respondents and take approximately 45 minutes each to complete. These estimates are based on the contractor's extensive experience with mental models research.

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>.

Dated: November 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-N-0474] (formerly Docket No. 2007N-0292)

George Kindness; 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 debaring Mr. George 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. 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 debaring 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.