

TABLE A.12-1 ESTIMATES OF HOUR BURDEN—Continued

Type of respondents	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Accepted Donors	* 12	1	0.5	6
Total	408	83.64

*These respondents are a subgroup of total 408 donors who will be initially contacted to participate in the study.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information Contact: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 9144, 6701 Rockledge Drive, Bethesda, MD 20892-7950, or call 301-435-0075, or E-mail your request to nemog@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: February 16, 2010.

George Nemo,

NHLBI Project Officer, NHLBI, National Institutes of Health.

[FR Doc. 2010-3449 Filed 2-22-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0585]

Patrick J. Lais: 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 Patrick J. Lais 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 Mr. Lais was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Lais has notified FDA that he acquiesces to debarment, and therefore has waived his opportunity for a hearing concerning this action.

DATES: This order is effective February 23, 2010.

ADDRESSES: Submit applications for special 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: Kenny Shade, Office of Regulatory Affairs (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6844.

SUPPLEMENTARY INFORMATION:

I. Background

On April 25, 2005, Mr. Patrick J. Lais, formerly president of York Pharmaceutical, pleaded guilty to introducing and delivering, and causing to be introduced and delivered into interstate commerce, a drug that was adulterated within the meaning of 21 U.S.C. 351(a)(2)(B) of the act, a felony under Federal law in violation of 21 U.S.C. 331(a) and 333(a)(2). Judgment was entered against him for this felony on August 15, 2005. The basis for this conviction was as follows:

Beginning in 1997 and lasting until September 2001, Mr. Lais was the president of York Pharmaceutical (York). Mr. Lais had responsibility for and authority over drug manufacturing at York. York manufactured generic over-the-counter drugs during the period January 1999 through July 2001.

York distributed in interstate commerce human drug products that

were adulterated within the meaning of 21 U.S.C. 351(a)(2)(B) of the act, in that York manufactured and distributed, among other things, subpotent burn spray, aspirin that had failed dissolution testing, and antacid products contaminated with bacteria.

Mr. Lais knew that York's manufacturing facility lacked basic validation processes and controls and that York's drug products were adulterated within the meaning of the act. Mr. Lais also knew that York: (1) Did not use procedures that ensured that its drugs had the identity, strength, quality, and purity characteristics that they were represented to possess; (2) did not test raw materials before using them; (3) did not perform appropriate laboratory determinations of conformance with final specifications for each of its drug products; (4) shipped drug product known not to meet established quality control criteria; (5) frequently failed to assess the stability characteristics of the drugs it produced; (6) did not maintain the buildings used in the manufacture, processing, packing, and holding of its drug products in a clean and sanitary condition; and (7) did not clean, maintain, and sanitize its manufacturing equipment and utensils in such a way as to prevent contamination of final drug products.

In January 2000, York manufactured and compressed a drug product identified as "Uncoated Aspirin." This drug failed its final dissolution testing. Neither Mr. Lais nor the employees under his authority and control determined the cause of the dissolution failure. Rather, York coated the failed aspirin and renumbered the lot. Part of this lot then was packaged as "Coated Aspirin." On or about February 21, 2000, Mr. Lais caused the shipment of 625 cases of adulterated drug products, identified as "Coated Aspirin," to customers in Kansas City, MO. In May 2000, this "Coated Aspirin" failed 3-month stability testing. Mr. Lais and the employees under his authority and control did not determine the cause of the failure and did not inform York's customers that the aspirin was adulterated.

Mr. Lais is subject to debarment based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 355a(a)(2)(B)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

In the plea agreement entered on April 25, 2005, Mr. Lais expressly waived his right, if any, to contest any debarment that may be initiated by the Secretary of Health and Human Services under 21 U.S.C.335a. In accordance with section 306(c)(2)(B) of the act, Mr. Lais notified FDA of his acquiescence to debarment in a letter signed on October 3, 2006. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act, but by acquiescing to debarment Mr. Lais waived his opportunity for a hearing and to raise any contentions concerning his debarment.

II. Findings and Order

Therefore, the Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the act, under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Patrick J. Lais has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding and based on his notification of acquiescence, Mr. Lais 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 October 3, 2006, the date of notification of acquiescence (see sections 306(c)(1)(B), (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 employs or retains as a consultant or contractor, or otherwise uses the services of Patrick J. Lais, in any capacity during Mr. Lais's debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Lais provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he 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 applications submitted by or with the assistance of Mr. Lais during his period of debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Lais for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA-2009-N-0585 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: January 26, 2010.

Brenda Holman,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2010-3552 Filed 2-22-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Automated Computer-Aided Polyp Detection for Computed Tomography Colonography (Virtual Colonoscopy)

Description of Invention: This invention describes an automated method for colon registration from supine and prone scans that combines the use of Computed Tomographic Colonography (CTC) and Computer Aided Detection (CAD) software.

Currently, in order to detect colonic polyps, patients are scanned twice—once in the supine, and again in the prone positions. This approach improves CTC sensitivity by reducing the extent of non-interpretable collapsed or fluid-filled segments. In order to assist radiologists in interpreting CTC data or evaluating colonic polyp candidates detected by CAD in both scans, it is important to provide not only the locations of suspicious polyps, but also the possible matched pairs (correspondences) of polyps in these scans. To achieve this, the two scans need to be aligned. In this invention, the colon registration problem is formulated as time series matching along the centerline of the colon. Anatomically salient points on the colon are initially distinguished as they can be viewed as landmarks along the central path of the colon. Correlation optimized warping is then applied to the segments defined by the anatomical landmarks to find better global registration based on the local correlation of segments.

When CTC is performed in conjunction with CAD software, screening may become easier on patients, less time-consuming, and more accurate. The effectiveness of the method was verified in experiments in which the polyp location was used as a measure for the registration error. The algorithm was tested on a CTC dataset of 12 patients with 14 polyps. Experimental results showed that by using this method, the estimation error of polyp location could be reduced 60.4% (from 47.2mm to 18.7mm on average) compared to a traditional method based on dynamic time warping.

Colon cancer is the second leading cause of cancer-related deaths in the United States, and the method used in this invention will aid in effective early detection of the disease, which will have a significant impact on its prognosis.

Applications: Efficient and robust detection of colon cancer.

Development Status: Early stage.

Inventors: Ronald M. Summers *et al.* (NIHCC).

Related Publication: Huang A, Roy D, Franaszek M, Summers RM. Teniae coli guided navigation and registration for virtual colonoscopy. Visualization, 2005. VIS 05. IEEE, pp. 279-285, 23-28 Oct 2005; doi 10.1109/VISUAL.2005.1532806.

Patent Status: U.S. Patent Application No. 61/220,481 filed June 25, 2009 (HHS Reference No. E-135-2009/0-US-01).

Licensing Status: Available for licensing.