Dated: Feb. 17, 2010.

Mara L. Vanderslice,

Special Assistant.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Investigating the Causes of Post Donation Information (PDI): Errors in the Donor Screening Process

SUMMARY: In compliance with the requirement of Section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Investigating the causes of post donation information (PDI): Errors in the donor screening process. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Blood centers are required to use a health history screening questionnaire to obtain eligibility information for the protection of the donor and recipient prior to blood donation. However, the health history process is known to be error-prone and the reasons for those errors are largely unknown and untested. Donors often fail to report a risk that would have resulted in deferral. This deferral risk may be disclosed at a subsequent donation and is classified as Post Donation Information (PDI). While this deferral risk may be at the next donation event, many examples of PDI are not disclosed nor discovered until several intervening donation events have occurred. The reasons why donors fail to disclose a deferrable history at the time of one donation but subsequently disclose this information at a later time are unidentified. This protocol is designed to ascertain why PDI error events occur. It will be the first study of any kind to address the issue of PDI errors in any systematic fashion. By conducting interviews with donors involved in PDI errors, we will gain important qualitative knowledge about this problem. Information gathered from these interviews will not only elucidate the issue of PDI but will provide insight into donor understanding of the screening process and their feelings about the process and blood donation in general.

The main objectives of the study are:

1. To explore reasons behind errors in the donor screening process when donors initially fail to disclose an accurate and complete health history.

2. To explore PDI donors' knowledge, attitudes, behaviors and beliefs (KABB) about the health history questionnaire and their experience with the screening process and the center.

3. To compare KABB in PDI donors to deferred (but not PDI) donors and accepted donors.

The study sample will consist of three donor groups:

1. Donors with a PDI: all identified donors of interest with an FDA reportable donor suitability error classified as PDI at the REDS–II centers

2. Deferred donors: appropriately deferred (but not PDI deferred donors) at the REDS–II centers

3. Accepted Donors: appropriately accepted for donation at the REDS–II centers

Telephone interviews will be conducted with consented donors to collect information regarding their knowledge, attitudes, behaviors and beliefs about the donor health history process. Even though the interviews with the donors will be individual, we would like to form groups of similar PDI and deferred donors for analysis purposes.

The five groups of interest include PDI occurrences or deferrals that are due to

- Travel (malaria, vCJD)
- Medical (history of diseases including jaundice/hepatitis, surgery and medications needed to treat disease including Tegison, Proscar and Accutane)
- Blood/Disease Exposure (tattoo, piercings, accidental needle stick)
- High Risk Behavior—Sexual (MSM, sex with IV drug-user or test-positive individual)
- High Risk Behavior—Non-Sexual (IV drug use, non-sexual exposure to Hepatitis C or Hepatitis B.

All interviews will be digitally-recorded and the recordings uploaded onto computers as dss files; these files will be transcribed and then coupled to the interviewer notes to form an analytic package for the data analysts. Once the interview is conducted successfully, each study donor will be mailed a check of $25 as an incentive for participating in the study.

The cognitive testing of the interview guide will be conducted at the Hoxworth Blood Center and at the Coordinating Center. For this purpose, the blood center staff will identify 2 PDI and 2 deferred donors from the five broad categories of interest. They will also contact 2 accepted donors for study consent and interview. These donors will be approached and consented by following the same procedures that will be used for the actual study.

The data from the semi-structured interviews will be analyzed in two ways. The close-ended responses will be analyzed quantitatively. This will likely take the form of 3-way cross-tabulations of frequency distributions in responses to key questions. The open-ended responses will be analyzed as qualitative data. All analytic steps and assumptions that led up to the conclusions, including competing interpretations of the data, will be fully discussed in the final report.

Frequency of Response: Once. *Affected Public: Individuals. Type of Respondents:* Adult blood donors. The annual reporting burden is a follows: *Estimated Number of Respondents:* 408; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.08 for the initial phone call and 0.5 for responding to the actual interview; and *Estimated Total Annual Burden Hours Requested:* 83.64. *The annualized cost to respondents is estimated at:* $1505.52 (based on $18 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Table 1: Estimate of Requested Burden Hours and Dollar Value of Burden Hours

TABLE A.12–1 ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Donors initially contacted	408	1	.08	32.6
PDI Donors	*60	1	0.5	30
Deferred Donors	*30	1	0.5	15

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.

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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.