

misconduct. With respect to the material identified in Paragraph 6, Dr. Dreyer admitted that he fabricated the 21 chromatograms contained in the magneto-optical computer disk that he provided to institutional officials after questions were raised about his research. Dr. Dreyer further admitted that the fabrication of the data on the disk amounts to scientific misconduct.

Dr. Dreyer has voluntarily agreed for a period of ten (10) years, beginning on November 15, 2000, to exclude himself from:

(1) Any contracting or subcontracting with any agency of the United States Government and from eligibility for, of involvement in, nonprocurement transactions (e.g., grants and cooperative agreements of the United States Government as defined in 45 CFR Part 76 (Debarment Regulations);

(2) Serving as a mentor to any graduate student, fellow, or other individual who applies for or receives Federal funding; and

(3) Serving in any capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

The above voluntary exclusion, however, does not apply to Dr. Dreyer's practice of clinical medicine as a licensed practitioner or to Federal funds used for purposes of teaching or training medical students, residents, or fellows, in clinical medical matters.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443-5330.

Chris Pascal,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organizations, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 65 FR 68144, dated November 14, 2000) is amended to revise the functional statement of the

Division for AIDS, STD, and TB Laboratory Research (DASTLR), National Center of Infections (NCID).

Section C-B, Organization and Functions, is hereby amended as follows:

Delete the functional statement for the Division of AIDS, STD and TB Laboratory Research (HCRN) and insert the following:

Division of AIDS, STD and TB Laboratory Research (HCRN). (1) Develops and evaluates laboratory methods and procedures for the diagnosis and characterization of infections caused by human immunodeficiency virus (HIV) and other retroviruses, other sexually transmitted diseases (STDs), and mycobacteria including *Mycobacterium tuberculosis*; (2) provides laboratory support for the surveillance, epidemiologic, and clinical activities of the National Center for HIV, STD, and TB Prevention (NCHSTP); (3) conducts applied research on the pathogenesis of and the immune mechanisms that occur in microbial infections; (4) conducts laboratory studies of hemophilia and other coagulating disorders; (5) provides reference laboratory services and assists in standardizing and providing laboratory reagents; (6) serves as a World Health Organization Collaborating Center; (7) conducts epidemiologic studies of HIV-infected and uninfected persons with hemophilia and their families; (8) assists in designing, implementing, and evaluating prevention and counseling programs for HIV-infected persons with hemophilia and their families; and (9) coordinates research on opportunistic infections occurring in HIV-infected persons.

Dated: November 15, 2000.

Jeffrey P. Koplan,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1599]

Agency Information Collection Activities; Proposed Collection; Comment Request; Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements to insure public health and safety for manufacturers of impact-resistant lenses used in eyeglasses and sunglasses.

DATES: Submit written or electronic comments on the collection of information by January 29, 2001.

ADDRESSES: Submit written or electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary

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for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses (OMB Control Number 0910-0182)—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), every manufacturer or importer of a device intended for human use shall establish and maintain records. This regulation is designed to protect the eyeglass and sunglass wearer from potential eye injury resulting from shattering of ordinary eyeglass lenses,

and it requires that eyeglasses and sunglasses be fitted with impact-resistant lenses. Section 801.410(f) (21 CFR 801.410(f)) requires that the results of impact tests and description of the test method and apparatus also be kept for a period of 3 years. These records are valuable to FDA when investigating eye injury complaints.

The expected respondents to this collection are manufacturers of impact-resistant lenses. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.410(f)	30	769,000	23,070,00	.0008	18,456

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

The Vision Council of America (www.visionsite.org) provided sales figures that were used in estimating the burden for this collection. Beginning in 1998, a growth rate of 2.6 percent for the distribution of lenses began, and it was assumed that this growth rate continued in 1999 and 2000. This resulted in an increase in the number of eyeglasses shipped annually to 89 million lenses shipped by year 2000.

By also assuming that the glass/plastic lenses-produced ratio remained as in previous years (22 percent glass and 78 percent plastic), that glass lenses must be tested individually, and only 5 percent of the plastic lenses must be tested, then 23,070,000 lenses should be tested. This figure was derived by taking 22 percent of 89 million glass lenses (19,600,000) and adding it to 5 percent of the remaining plastic lenses (5 percent x 69,400,000 = 3,470,000).

Next, divide the total tests (23,070,000) by 30 manufacturers to return the annual frequency of recordkeeping figure of 769,000. Previously, FDA and industry experts estimated that on average, each test could be completed and recorded in 3 seconds. Industry, therefore, could complete 1,200 tests per hour. Therefore, it is estimated that the total burden for this collection is 19,225 hours, which is calculated by taking the total records figure (23,070,000) and dividing it by tests per hour (1,200). The total hours was calculated by multiplying the total number of records (23,070,000) and the hours per record (.0008).

There is no burden estimated for maintaining sale or distribution records under § 801.410(e) since firms are

retaining their records as a normal and customary business practice for reasons of product liability.

Dated: November 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N-0220]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Substances Approved for Use in the Preparation of Meat and Poultry Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 28, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235,

Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT:

Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Petition for Approval of Substances for Use in the Preparation of Meat and Poultry Products—21 CFR 71.1 and 171.1

Sections 409 and 721 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348 and 379e) require FDA to evaluate the safety and regulate the use of food and color additives used as ingredients in or on all foods. These sections also authorize FDA to accept petitions for approval of food and color additives. The Federal Meat Inspection Act and the Poultry Products Inspection Act (21 U.S.C. 601(m)(2) and 453(g)(2), respectively) authorize the administration of the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture to determine the suitability of the use of a substance in meat and poultry products. Regulations of the two agencies regarding petition submissions at times include conditions, formats, and terms that are not fully consistent with one another because of the different statutory mandates. Under the current process, FDA and FSIS conduct separate, sequential reviews of petitions, each agency applying its respective