place where the review will occur, and other details.

Petitioners may, at any time on or before January 18, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: December 4, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–30815 Filed 12–18–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95M–0395]

Pharmacia, Inc.; Premarket Approval of Model WS–100 Pliolens Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Pharmacia, Inc., Dublin, OH, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Model WS–100 Pliolens ultraviolet-absorbing silicone posterior chamber intraocular lens. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of July 20, 1995, of the approval of the application.

DATES: Petitions for administrative review by January 18, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ashley A. Boulware, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053.

SUPPLEMENTARY INFORMATION: On February 28, 1994, Pharmacia, Inc., Dublin, OH 43017, submitted to CDRH an application for premarket approval of Model WS–100 Pliolens ultraviolet-absorbing silicone posterior chamber intraocular lens. The device is a posterior chamber intraocular lens and is indicated for primary implantation for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by extracapsular cataract extraction.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On July 20, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 18, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: November 29, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–30698 Filed 12–18–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0253J]

Analysis Regarding The Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; analysis regarding agency jurisdiction; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of August 11, 1995 (60 FR 41453). In the notice, FDA published a document entitled ''Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act,'' and announced the availability of appendices to this document. The agency has identified some proofreading inaccuracies in the references listed in the document. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Phillip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

In FR Doc. 95–20052, appearing on page 41453 in the Federal Register of

August 11, 1995, the following corrections are made:

1. On page 41556, in footnote 89, ''1588'' is corrected to read ''1558,'' and on the same page, in footnote 90, in line 1, ''MDG'' is corrected to read ''MDB''.

2. On page 41557, in footnote 91, in line 1, the phrase ''of behavioral dependence'' is corrected to read ''of and behavioral dependence''.

3. On page 41558, in footnote 93, in line 4, ''*Parmacol. Biochem. Behav.*'' is corrected to read ''*Pharmacol. Biochemistry & Behav.*''

4. On page 41560, in footnote 101, in line 4, ''Page 50'' is corrected to read ''Pages 50–51.''

5. On page 41561, in footnote 105, in line 2, ''231–234'' is corrected to read ''231–241.''

6. On page 41588, in footnote 172, in line 8, ''12641–46'' is corrected to read ''02641–02646''.

7. On page 41621, in footnote 240a, in line 13, ''July 25, 2995'' is corrected to read ''July 25, 1995).''

Dated: December 12, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–30745 Filed 12–18–95; 8:45 am]

BILLING CODE 4160–01–F

Public Health Service

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 59 FR 17106, April 11, 1994) is amended to reflect the following reorganization within the Center for Devices and Radiological Health (CDRH), Office of Operations, Food and Drug Administration (FDA).

The Center for Devices and Radiological Health is abolishing the Office of Health Physics (OHP), the Office of Health Affairs (OHA), and the Office of Standards and Regulations (OSR) and realigning their functions into existing line and staff offices within the Center. The goal of this realignment is to more effectively manage the resources invested in these functional areas, consolidate similar functions, realign medical expertise closer to program needs, and streamline the current organizational structure.

Under section HF-B, Organization:

1. Delete subparagraphs Office of Health Physics (HFW12), the Office of Health Affairs (HFW13), and the Office of Standards and Regulations (HFW14) under paragraph Center for Devices and Radiological Health (HFW), in their entirety.

2. Insert the following new subparagraphs under paragraph *Office of Operations (HFA9), Center for Devices and Radiological Health (HFW)* reading as follows:

Office of Systems and Management (HFW11). Advises the Center Director regarding all administrative management matters.

Plans, develops, and implements Center management policies and programs concerning financial and human resource management, contracts and grants management, conference management, occupational safety, organizational, and general office services support.

Develops and implements the Center's long-range, strategic, and operational plans.

Develops and applies evaluation techniques to measure the effectiveness of Center programs.

Provides general information and technical publication services to the Center.

Plans, conducts, and coordinates Center committee management activities.

Determines and implements Center strategy and utilization of information management resources.

Designs administrative, scientific, and technical information systems in support of Center programs.

Provides assistance to Center staff in accessing information necessary to carry out the Center's mission.

Coordinates requests and Center activities pertaining to the Freedom of Information and Privacy Acts.

Office of Health and Industry Programs (HFWG). Analyzes medical device and radiation-emitting product user-related problems and conducts research, applying systems analysis and human factors to problem identification and solution strategies. Implements and evaluates user-related solution strategies.

Conducts and evaluates programs to provide technical and other nonfinancial assistance to small manufacturers of medical devices to promote their understanding of compliance with the medical device amendments and regulations.

Provides, maintains, and applies expertise in communications technology in support of Center and FDA programs.

Develops and implements strategies for obtaining, analyzing, and incorporating the views and needs of health professionals, lay device users, and industry into the Center policy and decision-making processes as well as in problem analysis, resolution strategy development, implementation, and evaluation processes.

Establishes and operates a program to implement the Mammography Quality Standards Act of 1992.

Provides leadership and technical expertise to the Center and other Departmental components in applying health physics procedures and radiation protection principles.

Advises the Center Director and appropriate Agency officials on FDA regulation development responsibilities relating to medical devices and radiological health activities. Serves as the Center focal point for liaison on regulations development activities with the Office of General Counsel.

Coordinates the development, review and submission of Federal Register publications for the Center. Prepares position statements for the Center on standards promulgated by other organizations.

Coordinates international relations activities as required by the Safe Medical Devices Act of 1990.

Office of Science and Technology (HFWE). Provides scientific support and laboratory analyses in response to the program needs of other Center and Agency components.

Plans, develops, and implements an intramural science program covering key areas of engineering, physics, and biology; develops, modifies, and validates test methods and measurement techniques, risk assessments and hazard analyses, and generic techniques to enhance product safety and usefulness.

Provides scientific and engineering support in the review of regulatory documents, the development of regulatory decisions, and the analysis of postmarket surveillance issues.

Plans, conducts, or stimulates research on the human health effects of radiation and medical devices.

Participates in the development of national and international consensus standards and voluntary guidelines through interaction with appropriate standards committees; coordinates with other standards-setting groups representing national and international standards-setting organizations; conducts the review and analysis of performance standards, guides and documents related to the Center's mission.

Establishes official liaisons with Standards Development Organizations. Coordinates the liaison within the Center. Establishes and maintains