tablets is used for the relief of symptoms such as sneezing, watery eyes, blocked or runny nose, that occur with hayfever (seasonal allergic rhinitis). The application was received and filed in the Center for Drug Evaluation and Research on August 10, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by September 7, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: August 14, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–21224 Filed 8–25–95; 8:45 am]

BILLING CODE 4160–01–F

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 53 FR 8978, March 18, 1988) is amended to reflect the following reorganization in the Food and Drug Administration (FDA).

The functional statements for the Office of Compliance, Center for Drug Evaluation and Research (CDER), are being revised and updated to more accurately reflect the activities carried out by this Office.

Under section HF–B, Organization:

1. Delete the subparagraph, Office of Compliance (HFND), under the Center for Drug Evaluation and Research (HFN) and insert a new subparagraph reading as follows:

Office of Compliance (HFND). Monitors the quality of marketed drugs, including nontraditional drugs, through product testing, surveillance, and compliance programs.

Develops policy and standards for labeling, current good manufacturing practice issues, clinical and good laboratory practice investigations, postmarketing surveillance, and drug industry practices to demonstrate the safety and effectiveness of human drug products and ensures the uniform interpretation of such standards.

Develops and directs drug product quality enforcement programs; postmarketing drug quality surveillance programs; and compliance programs for over-the-counter (OTC), nontraditional, and other drug monographs. Directs the Center's bioresearch monitoring program for human drug products.

Advises the Center Director and other Agency officials on FDA's regulatory and enforcement responsibilities for human drugs.

Initiates Center-field surveillance assignments to monitor pivotal research data submitted as part of premarketing applications. Coordinates preapproval inspections and results as part of the final product approval process.

Coordinates Center-field relations; provides support and guidance to the field on legal actions, case development, and contested cases; and reviews and decides disposition of field submissions involving deviations from standards.

Evaluates, classifies, and recommends human drug recalls and provides Center coordination with field recall activities. Monitors the resolution of all drug shortage situations involving compliance issues.

Coordinates international inspections, results, and communications with inspectorates of other nations. Participates in international standards-setting activities.

5. Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: August 14, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–21263 Filed 8–25–95; 8:45 am]

BILLING CODE 4160–01–M

Health Care Financing Administration

[HSQ–230–N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Permit-Holding Laboratories in the State of New York

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: Section 353(p) of the Public Health Service Act provides for the exemption of laboratories from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) when the State in which they are located has requirements equal to or more stringent than those of CLIA. This notice grants exemption from CLIA requirements applicable only to laboratories located within the State of New York, including New York City, that possess a valid permit, as mandated under Part 58, and Article Five of Title V of the Public Health Law of the State of New York. This title is applicable to all laboratories except those operated by an individual, licensed physician, osteopath, dentist, podiatrist, or a physician's group practice which performs laboratory tests personally or through his or her employees, solely as an adjunct to the treatment of his or her own patients.

EFFECTIVE DATE: The provisions of this notice are effective on August 28, 1995 to June 30, 2001.

FOR FURTHER INFORMATION CALL: Val Coppola, (410) 786–3406.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 353 of the Public Health Service Act (PHS Act), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), requires any laboratory that performs tests on human specimens to meet requirements established by the Department of Health and Human Services (HHS). Under the provisions of the sentence following section 1861(s)(14) and paragraph (s)(16) of the Social Security Act, any laboratory that also wants to be paid for services furnished to Medicare beneficiaries must meet the requirements of section 353 of the PHS Act. Subject to specified exceptions, laboratories must have a current and valid CLIA certificate to test human specimens and to be eligible for payment from the Medicare or Medicaid program. Regulations implementing