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

section 353 of the PHS Act are contained in 42 CFR part 493.

Section 353(p) of the PHS Act provides for the exemption of laboratories from CLIA requirements in a State that applies requirements that are equal to, or more stringent than, those of CLIA. The statute does not specifically require the promulgation of criteria for the exemption of laboratories in a State. The decision to grant CLIA exemption to laboratories within a State is at our discretion, acting on behalf of the Secretary of HHS.

Part 493, subpart E, implements section 353(p) of the PHS Act. Section 493.513 provides that we may exempt from CLIA requirements, for a period not to exceed 6 years, State licensed or approved laboratories in a State if the State meets specified conditions. Section 493.513(k) provides that we will publish a notice in the **Federal Register** announcing the names of States whose laboratories are exempt from meeting the requirements of part 493.

II. Notice of Approval of CLIA Exemption to New York State Laboratories

In this notice, we grant CLIA exemption for all specialties and subspecialties to all laboratories located in the State of New York, including New York City, that possess a valid permit to perform laboratory testing effective August 28, 1995 to June 30, 2001.

III. Evaluation of New York State (NYS) Laboratories

The following describes the process we used to determine whether we should grant exemption from CLIA requirements to permit-holding NYS laboratories.

A. Requirements for Granting CLIA Exemption

To determine whether we should grant a CLIA exemption to all laboratories within the State of New York, we conducted a detailed and in-depth comparison of NYS' requirements for its laboratories to those of CLIA and evaluated whether NYS' standards meet the requirements at § 493.513. In summary, we evaluated whether NYS—

- Has laws in effect that provide for requirements that are equal to, or more stringent than, CLIA requirements;
- Has an agency that licenses or approves laboratories meeting State requirements that also meet or exceed CLIA requirements, and would, therefore, meet the condition level requirements of the CLIA regulations;
- Demonstrates that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements;
- Permits us or our agents to inspect laboratories within the State;
- Requires laboratories within the State to submit to inspections by us or our agents as a condition of licensure;
- Agrees to pay the cost of the validation program administered by us and the cost of the State's pro rata share of the general overhead to develop and implement CLIA as specified in §§ 493.645(b) and 493.646; and
- Takes appropriate enforcement action against laboratories found by us or our agents not to be in compliance with requirements comparable to condition level requirements.

We also evaluated whether NYS laboratories meet the requirements and are approved in accordance with § 493.515, Federal review of laboratory requirements of State laboratory programs.

As specified in § 493.515, our review of a State laboratory program includes (but is not necessarily limited to) an evaluation of—

- Whether the State's requirements for laboratories are equivalent to, or more stringent than, the condition level requirements;
- The State's inspection process requirements to determine—

—The comparability of the full inspection and complaint inspection procedures to our procedures;
—The State's enforcement procedures for laboratories found to be out of compliance with its requirements; and
—The ability of the State to provide us with electronic data and reports with the adverse or corrective actions resulting from proficiency testing (PT) results that constitute unsuccessful participation in HCFA-approved PT programs and with other data we determine to be necessary for validation and assessment of the State's inspection process requirements;

- The State's agreement to—

—Notify us within 30 days of the action taken against any CLIA-exempt laboratory that has had its licensure or approval withdrawn or revoked or been in any way sanctioned;
—Notify us within 10 days of any deficiency identified in a CLIA-exempt laboratory in cases when the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public;
—Notify each laboratory licensed by the State within 10 days of our withdrawal of the exemption;
—Provide us with written notification of any changes in its licensure (or approval) and inspection requirements;
—Disclose any laboratory's PT results in accordance with a State's confidentiality requirements;
—Take the appropriate enforcement action against laboratories we find not to be in compliance with requirements comparable to condition level requirements and report these enforcement actions to us;
—Notify us of all newly licensed laboratories, including the specialties and subspecialties, for which any laboratory performs testing, within 30 days; and
—Provide to us, as requested, inspection schedules for validation purposes.

B. Evaluation of the New York State Request for CLIA Exemption

The State of New York has formally applied to us for an exemption from the CLIA requirements for the permit-holding laboratories located within the State, including those in New York City. This exemption does not apply to laboratories outside of the State of New York that possess a NYS permit to perform laboratory testing on specimens from NYS residents. In addition, this exemption does not apply to laboratories 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.

We have evaluated the NYS CLIA exemption application and all subsequent submissions for equivalency against the three major categories of CLIA rules: The implementing regulations, the enforcement regulations, and the deeming/exemption requirements. We found the NYS Clinical Laboratory Evaluation Program, which issues, implements, and enforces regulations specified in Part 58 and Article Five of Title V of the Public Health Law of the State of New York, to administer a program that is more stringent than the CLIA program, taken as a whole. Rather than enumerating every more stringent item of the NYS requirements, we have included in this notice the more significant and exemplary areas of stringency. We performed an indepth evaluation of the NYS application to verify the State's assurance of compliance with the following subparts of part 493.

Our evaluation identified more stringent areas of the NYS requirements that apply to the laboratory as a whole. Rather than include them in the appropriate subparts multiple times, we list them here:

• NYS has extensive requirements involving laboratory safety. They include detailed standards for biosafety, chemical safety, radiological safety and regulated medical waste.

• NYS permit holding laboratories that use a laboratory information system (LIS) for any aspect of specimen testing, reporting, and/or record keeping must adhere to all applicable provisions of part 58 and including, but not limited to, the following:

—Test results are reported, archived, and maintained in an accurate and reliable manner.
—Performance and documentation of system maintenance required by the LIS manufacturer, or established and validated by the laboratory.
—All devices are maintained to ensure accurate, clear, and interference-free report transmissions.
—New or revised software and/or hardware is validated prior to use.
—Written back-up procedures are available for test reporting and retrieval when the LIS is out of service.
—The LIS is capable of generating an exact duplicate of a final test report and any preliminary report.
—LIS data and programs are protected from unauthorized use.

• NYS regulations provide requirements for forensic testing to include PT when applicable.

• NYS regulations list requirements covering paternity testing as well as workplace drug testing.

Subpart E, Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under An Approved State Laboratory Program

HCFA and the Centers for Disease Control and Prevention (CDC) staff reviewers have examined the NYS application and all subsequent submissions against the exemption requirements a State must meet in order to be granted CLIA exempt status (§ 493.513, and the applicable parts of §§ 493.515, 493.517, 493.519, and 493.521). The State has complied with the applicable CLIA requirements for exemption under this subpart.

Subpart H, Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity, (Including the Subcategory), High Complexity, or Any Combination of These Tests

The statute and implementing regulations of NYS for PT are more stringent than those of CLIA. Permit-holding laboratories are required by NYS statute to participate in the NYS PT program for all testing performed, provided it is offered by the program. Laboratories must enroll and participate in PT for all testing regardless of the CLIA categorization of waived, moderate, or high complexity. The PT testing available through the NYS PT program is much more extensive than the list of tests included in the CLIA regulations. The NYS program offers many more analytes, as well as additional specialties and subspecialties beyond those in the CLIA requirements.

The NYS PT program, which we have approved under CLIA, meets the requirements of subpart I, Proficiency Testing Programs for Tests of Moderate or High Complexity or Both, and in some areas, exceeds the CLIA PT program requirements. The passing scores are higher than those of CLIA for human immunodeficiency virus testing and for antibody detection and antibody identification. Because the PT program is a part of the CLIA exemption application, the State may include PT requirements that are equal to or more stringent than those of CLIA.

PT performance is closely monitored by the NYS Clinical Laboratory Evaluation Program. If a laboratory fails a particular PT event, the laboratory is notified in writing. If a laboratory fails two consecutive or two of three PT events (unsuccessful performance), the laboratory must stop testing for the unsuccessful category and/or analyte.

Laboratories that wish to add a category or a test to a permit must successfully complete two consecutive PT testing events prior to the initiation of patient testing. New laboratories must also participate successfully in two events before testing patient specimens. The CLIA regulations do not contain such requirements.

Subpart J, Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

The NYS requirements for patient test management are more stringent than those of CLIA. Areas of stringency that exceed CLIA requirements are:

• Oral test requests are followed by a written request within 48 hours. If not received in this timeframe, the requestor is notified and the written authorization received within 30 days.

• Retention records for test requests, accession records and laboratory reports is 7 years; however, pathology reports must be retained for 20 years, and cytogenetics and genetic testing reports must be held for 25 years.

• State permit-holding laboratories may only refer specimens for testing to other laboratories that hold applicable State permits.

• A specimen received by a laboratory must not be tested or results reported if—

—It is unsatisfactory or inappropriate for the test requested;
—It has been collected, labeled, preserved, stored, transported or otherwise handled in a manner that caused it to become unsatisfactory or unreliable as a test specimen;
—It is labile and the time lapse between collection and receipt is such that it may no longer be reliable;
—The date and hour of collection, when required by the method or procedure, are not furnished; and
—The test is investigational and the laboratory does not have authorization from both the ordering individual and the patient indicating their awareness of the test limitations and investigational nature before the test is performed;

• Specific confidentiality protocols are required that must include—

—A definition of confidential information and prohibition of unauthorized access;
—The responsibilities of the director/assistant director to determine appropriate release and access to information;
—The responsibilities of employees;
—The contents of required in-service training programs;
—A mechanism for documenting attendance and attestation statements from each employee who is authorized to access confidential information; and
—The consequences of violation of confidentiality requirements which may include criminal prosecution.

• Laboratories must not report the results of a test on a specimen unless the test request information listed in the regulations has been obtained; and

• Specific requirements are listed for patient service centers (specimen collection).

Subpart K, Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

The NYS requirements on quality control (QC) are more stringent than CLIA requirements as all testing including waived tests under CLIA must meet all QC requirements for high complexity testing. NYS has never allowed a phase-in for any of its QC requirements.

NYS permitted laboratories must perform method validation before a test procedure is placed into routine use and

maintain documentation of the validations of all procedures while they are in use. The linear reportable range must be established or verified for all applicable procedures. Three levels of controls must be employed for quantitative chemistry testing if calibration is not performed or validated within a run of more than 24 hours. Trilevel controls are required for quantitative immunology testing. HIV testing must be a repeatable positive and a confirmatory test performed by an appropriately permitted NYS laboratory before reporting a positive result.

The items listed above are more stringent requirements and exemplify the QC contents of the NYS program which, taken as a whole, are more stringent than the QC requirements of CLIA.

Subpart M, Personnel for Moderate Complexity (Including the Subcategory) and High Complexity Testing

The personnel requirements of NYS are more stringent than those of CLIA, taken as a whole. CLIA allows lesser qualified individuals to direct a laboratory performing moderate complexity tests, compared to the qualification requirements for individuals directing a laboratory in which high complexity testing is performed. CLIA has no requirements for an individual or laboratory engaged in waived test performance. NYS treats all testing in a manner similar to CLIA's high complexity tests. Therefore, NYS does not allow a laboratory to be directed by individuals possessing appropriate qualifications for CLIA's moderate test performance, nor does it allow a laboratory to be directed by individuals possessing the qualifications for waived test performance.

Individuals who wish to direct a permit holding laboratory must obtain a Certificate of Qualification through the Clinical Laboratory Evaluation Program. They must formally apply and submit documentation of professional and academic expertise in all the specialties and subspecialties for which the laboratory conducts testing and holds a NYS permit. The documentation is evaluated and approved by the Clinical Laboratory Evaluation Program professional staff, in accordance with the NYS Public Health law and regulations.

Subpart P, Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests

The applicable standards of the NYS regulations have been revised and are equivalent to the CLIA requirements at §§ 493.1701 through 493.1721 concerning quality assurance. NYS does, however, require laboratories to evaluate and define the relationship between the same test by different methods or different instrument three times per year. CLIA requires this evaluation twice a year.

Subpart Q, Inspection

The NYS permit-holding laboratories are routinely inspected on-site biennially. Routine inspections and complaint inspections are performed on an unannounced basis. Inspection for a laboratory first entering the program is scheduled after the facility has notified the Clinical Laboratory Evaluation Program that it is prepared to begin patient testing. A new laboratory will not receive a NYS permit until an on-site inspection is performed and all identified deficiencies have been corrected. This requirement and the use of unannounced compliance inspections are more stringent than those of CLIA. We conduct compliance inspections to monitor the correction of deficiencies and ensure that laboratories continue to meet State standards.

NYS also uses a protocol similar to that of HCFA for complaint investigations involving laboratories performing cytopathology. This inspection focuses on all cytology requirements and, if indicated, retrospective rescreens of previously read cytology cases are performed.

Subpart R, Enforcement Procedures

We have reviewed documentation of the State's enforcement authority, its administrative structure and the resources used to enforce its standards for completeness. The State appropriately applies limitations and revocations of its permits for laboratories as well as intermediate sanctions such as on-site monitoring of laboratories and imposition of civil money penalties.

The State has provided us with the mechanism it currently uses to monitor the PT performance of its laboratories. The action NYS takes for unsuccessful PT participation is more stringent than those of CLIA's enforcement policy. A permitted laboratory must suspend testing for the unsuccessful analyte or category until it successfully remediates the problem area. The State has provided appropriate documentation demonstrating that its enforcement policies and procedures are equivalent to those of CLIA.

IV. Federal Validation Inspections and Continuing Oversight

We will conduct the Federal validation inspections of CLIA-exempt laboratories, as specified in § 493.517, on a representative sample basis as well as in response to substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections will be our principal means for verifying the appropriateness of the exemption given to laboratories in NYS. This Federal monitoring is an on-going process. The State of New York will provide us with survey findings for each laboratory selected for validation.

V. Removal of Approval of New York State Exemption

We will remove the CLIA exemption of laboratories located in NYS that possess a valid permit if we determine the outcome and comparability review of validation inspections are not acceptable, as described under § 493.521, or if the State fails to pay the required fee every 2 years as required under § 493.646.

VI. Laboratory Data

In accordance with § 493.513(d)(2)(iii), NYS will provide us with changes to a laboratory's specialties or subspecialties based on the State's survey and with changes in a laboratory's permit status.

VII. Required Administrative Actions

CLIA is intended to be generally a user-fee funded program. The registration fee paid by the laboratories is intended to cover the cost of the development and administration of the program. However, when a State's application for exemption is approved, we may not charge a fee to laboratories in the State that are covered by the exemption. We will collect the State's share of the costs associated with CLIA from the State. Section 493.645 specifies that HHS will assess fees that a State must pay for the following:

- Costs of Federal inspection of laboratories in the State to verify that standards are enforced in an appropriate manner. The average cost per validation survey nationally is multiplied by the number of surveys that will be conducted.
- Costs incurred for Federal investigations and surveys triggered by complaints that are substantiated. We

will bill the State on an semi-annual basis. We anticipate that most of these surveys will be referred to the State and that there will be little Federal activity in this area.

- The State's proportionate share of general overhead costs for the items and services it benefits from and only for those paid for out of registration or certificate fees we collected.

In order to estimate the State's proportionate share of the general overhead costs, we determined the ratio of laboratories in the State to the total number of laboratories nationally. In that the general overhead costs apply equally to all laboratories, we determined the cumulative overhead costs that should be borne by the State of New York.

The State of New York has agreed to pay us its pro rata share of the overhead costs and anticipated costs of actual validation and complaint investigation surveys. A final reconciliation for all laboratories and all expenses will be made. We will reimburse the State for any overpayment or bill it for any balance.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: August 2, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95–21264 Filed 8–25–95; 8:45 am]

BILLING CODE 4120–01–P

Public Health Service

Centers for Disease Control and Prevention; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HC (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–67776, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 60 FR 34550–51, dated July 3, 1995) is amended to reflect (1) the establishment of the Office of Health Communication within the Office of the Director, National Center for Injury Prevention and Control (NCIPC); and (2) the revision of the functional statement for the Office of Statistics, Programming, and Graphics; and (3) the retitling of the Office of Statistics, Programming, and Graphics to the Office of Statistics and Programming.

Section HC–B, *Organization and Functions*, is hereby amended as follows:

After the functional statement for the *Office of Program Management and Operations (HCE13)*, insert the following:

Office of Health Communication (HCE14). (1) Plans, develops, coordinates, and evaluates NCIPC's marketing, public affairs, publications, graphics, and technical information activities for intentional injury, unintentional injury, and acute care and rehabilitation; (2) in conjunction with the CDC Office of Health Communication, collaborates with organizations in the public and private sectors to market injury prevention and control messages; (3) develops educational material on injury prevention and control, including print and video products, to be used in the center's marketing activities; (4) disseminates injury control information to public and professional audiences; (5) in conjunction with the CDC Office of Public Affairs, interacts with the news media to ensure that injury topics are covered accurately and remain high on the public agenda; (6) provides expert consultation on the effective use and design of graphic materials for presentations, publications, and exhibits; (7) designs and produces professional quality graphic materials for use in NCIPC presentations and publications and designs and electronically typesets publications; (8) develops, maintains, and manages a graphics information retrieval system that allows ready access to slides and graphic presentations on injury topics; (9) provides expert consultation on the development and production of publications; (10) manages the clearance, editing, and production of NCIPC publications; (11) manages NCIPC's technical information resources, including developing and maintaining injury-related databases and a library of information on injury-related topics; (12) coordinates the center's information sharing activities, including involvement on INTERNET; (13) serves as NCIPC liaison with the CDC Office of Public Affairs, the CDC Office of Health Communication, and other Centers, Institute, and Offices on matters of marketing, public affairs, graphics, publications, and technical information resources; (14) in carrying out these functions, collaborates with other PHS agencies, Federal and State departments and agencies, and private organizations, as appropriate.

Office of Statistics and Programming (HCE2). (1) Develops, evaluates, and implements innovative statistical, computer programming, and data management methods for application to injury surveillance, epidemiologic studies, and programmatic activities; (2) provides expert consultation in statistics, programming, and data management to all NCIPC staff; (3) collaborates with NCIPC scientists on epidemiologic studies and provides associated technical advice in the areas of study design, sampling, and the collection, management, analysis, and interpretation of injury data; (4) coordinates, manages, maintains and provides tabulations from national surveillance systems and other data sources that contain national, State and local data on injury morbidity and mortality; (5) prepares and produces high quality statistical reports and publications material for information presentation and dissemination by NCIPC staff; (6) advises the Office of the Director, NCIPC, in the area of data and systems management and on surveillance and statistical analysis issues relevant to injury program planning and evaluation; (7) in carrying out the above functions, collaborates with other Divisions/Offices in NCIPC, CDC Centers/Institute/Offices, PHS agencies, and other Federal departments and agencies, and private organizations as appropriate.

Office of the Director (HCE21). (1) Plans, directs, and manages the activities of the Office of Statistics and Programming and provides administrative and management support; (2) reviews reports, publications, and other materials for statistical integrity and validity; (3) makes recommendations and provides technical advice to the Office of the Director, NCIPC, on statistical and surveillance issues relevant to injury prevention and control; (4) coordinates Office activities with other Offices and Divisions within NCIPC, other CDC components, PHS agencies, other Federal agencies, State and local health departments, and other public and private organizations, as appropriate.

Effective Date: August 15, 1995.

David Satcher,

Director, Centers for Disease Control and Prevention.

[FR Doc. 95–21301 Filed 8–25–95; 8:45 am]

BILLING CODE 4160–18–M