the subject of this **Federal Register** notice are intended for the second phase of the EHS evaluation.

The sample for the assessments will be approximately 1,360 fathers from the 3,400 EHS sample families, whose mothers and infants/toddlers are participating in the study (see OMB #0970-0143) in 17 EHS study sites. Each family will be randomly assigned to a treatment group or a control group. The assessments will be conducted through personal interviewing, structured observations and videotaping. All data collection instruments have been designed to minimize the burden on respondents by minimizing interviewing and assessment time. Participation in the study is voluntary and confidential.

The information will be used by government managers, Congress and others to better understand the roles of fathers and father-figures with their children and in the EHS program.

Respondents: Fathers or father-figures of children whose families are in the EHS national evaluation sample (both program and control group families).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	average burden hours per response	Total burden hours
24-Month Father Interview	635	1	10	635
Father-Child Videotaping Protocol	168	1	0.3	50
Estimated Total Annual Burden	.....	.....	.....	685

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having it full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Desk Officer for the Administration for Children Families.

Dated: September 29, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–26349 Filed 10–3–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegations of Authority

Notice is hereby given that I delegate to the Assistant Secretary for Children and Families, with authority to redelegate, the following authorities vested in the Secretary under the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, P.L. 104–193, as amended now and hereafter.

(a) Authorities Delegated:

(1) Authority to administer the provisions of Title I, Block Grants for Temporary Assistance for Needy Families (TANF) under Sections 101–103, 106–110, 112, 115 and 116 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, 42 U.S.C. 1305 note, 42 U.S.C. 601 *et seq.*, and as amended now and hereafter. In addition, in exercising authority under Section 103, ''Section 413, Research, Evaluations, and National Studies,'' of the Social Security Act, the Administration for Children and Families is expected to consult with the Assistant Secretary for Planning and Evaluation.

(2) Authority to administer the provisions of the Child Care and Development Block Grant Amendments of 1996, 42 U.S.C. 9801 note, under Sections 601–615 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, 42 U.S.C. 1305 note, 42 U.S.C. 601 *et seq.*, and as amended now and hereafter.

(b) Effect on existing delegations. None.

These delegations shall be exercised under the Department's existing delegation of authority and policy on regulations. These delegations of authority are effective upon date of signature. In addition, I hereby, affirm and ratify any actions taken by the Assistant Secretary for Children and Families or any other Administration for Children and Families official which, in effect, involved the exercise of these authorities prior to the effective date of these delegations.

Dated: September 16, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–26346 Filed 10–3–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0397]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 reinstatement 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 for manufacturers, importers, distributors, and retailers of impact-resistant lenses, including eyeglasses and sunglasses.

DATES: Submit written comments on the collection of information by December 5, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration,

12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, 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 reinstatement 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 listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary 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—21 CFR 801.410(e) and (f)—(OMB Control Number 0910–0182)—Reinstatement

FDA has the statutory authority under sections 501, 502, and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351, 352, and 371(a)) to regulate medical devices. Section 801.410 (21 CFR 801.410) requires that lenses be rendered impact-resistant and capable of withstanding the impact test referred to as the ''referee test'' in the regulation. Under § 801.410(c)(1), eyeglasses and sunglasses must be fitted with impact-resistant lenses except in cases where an optometrist or physician finds that such lenses will not fulfill a patient's visual requirements.

Under § 801.410(e) and (f), manufacturers and distributors of impact-resistant lenses, both eyeglasses and sunglasses, are required to maintain certain records. Under § 801.410(e) manufacturers, distributors, retailers, and importers are required to maintain records such as invoice(s), shipping documents, and records of sale or distribution of all impact-resistant lenses, including finished prescription eyeglasses and sunglasses, which shall be kept and maintained for a period of 3 years. However, the names and addresses of individuals purchasing nonprescription eyeglasses and sunglasses at the retail level need not be kept and maintained by the retailer. Under § 801.410(f) any persons conducting ''referee'' (lens impact) tests in accordance with § 801.410(d) shall maintain the results thereof and a description of the test method and of the test apparatus for a period of 3 years.

These records are valuable to FDA when investigating complaints (i.e., eye injury complaints). If records were not maintained, FDA investigations would be made more difficult to conduct and ultimately the public would not have the necessary protection from substandard eyeglasses. The regulation is designed to protect the eyeglass wearer from potential eye injury resulting from shattering of ordinary eyeglass lenses. Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer. Between 50 and 60 percent of the American public wear prescription eye wear.

Firms subject to this regulation are not required to submit the written records to FDA. FDA normally reviews and may copy records during an inspection of the manufacturer. The manufacturers are required to have the records available to FDA on an ''as needed'' basis.

Respondents to this collection of information are manufacturers, importers, distributors, and retailers of impact-resistant sunglasses and eyeglasses.

The burden of maintaining sale and/or distribution records, as required by § 801.410(e), is estimated at 0 hours since firms are routinely retaining the records beyond the 3-year period for reasons of routine business practice. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the recordkeeping needed to comply is usual and customary because it would occur in the normal course of activities.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.410(f)	30	590,000	17,700,000	492	14,760

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

There are approximately 30 manufacturers of eyeglasses in the U.S. Optical Manufacturers Association (OMA), which represents 98 percent of the domestic industry involved in lens manufacturing, and the association has stated to FDA that the regulation does not impose a burden on their members. This position is based on the fact that the recordkeeping and testing requirements of the regulation represent minimum requirements for a conscientious manufacturer.

Section 801.410(c)(1) states:

To protect the public more adequately from potential eye injury, eyeglasses and sunglasses must be fitted with impact-resistant lenses, except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs in writing the use of other lenses, and gives written notification thereof to the patient.

Optometrists in the Center of Devices and Radiological Health's Office of Device Evaluation, FDA, have estimated that it should take a physician or optometrist approximately 2 minutes to write up a prescription and notification

for nonimpact-resistant lenses. Because most prescription orders are now filled by impact-resistant plastic lenses, and only one or two orders for nonimpact-resistant lenses are estimated to be completed annually, this de minimus burden is not included in the chart.

Dated: September 29, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–26451 Filed 10–3–97 ; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0384]

Knickerbocker Biologicals, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 458–001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the establishment license (U.S. License No. 458–001) and product licenses issued to Knickerbocker Biologicals, Inc., for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Source Leukocytes. The proposed revocation is based on the inability of authorized FDA employees to conduct an inspection of this facility, which is no longer in operation.

DATES: The firm may submit written requests for a hearing to the Dockets Management Branch by November 5, 1997, and any data and information justifying a hearing by December 5, 1997. Other interested persons may submit written comments on the proposed revocation by December 5, 1997.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke the establishment license (U.S. License 458–001) and product licenses issued to Knickerbocker Biologicals, Inc., doing business as Knickerbocker Blood Bank, 272 Willis Ave., Bronx, NY 10454, for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Source Leukocytes. Proceedings to revoke the licenses are being initiated because an attempted inspection of the facility by FDA revealed that the firm was no longer in operation.

In a certified, return-receipt letter dated November 14, 1996, FDA notified the Responsible Head of the firm that its attempt to conduct an inspection at Knickerbocker Biologicals, Inc., at 272 Willis Ave., Bronx, NY 10454, was unsuccessful because the facility was apparently no longer in operation, and requested that the firm notify FDA in writing of the firm's status. This letter was returned to the agency marked ''undeliverable; address unknown.''

On December 3, 1996, FDA visited three other known addresses of Knickerbocker Biologicals, Inc., New York, NY, and attempted to conduct an inspection. These attempts were also unsuccessful. Upon consultation, the U.S. Postal Service reported no information regarding a forwarding address or change of address for any of the last known locations.

In a certified, return-receipt letter sent to Knickerbocker Biologicals, Inc., dated January 24, 1997, and returned as undeliverable, FDA indicated that the attempts to conduct an inspection at the facility were unsuccessful. The letter also advised the Responsible Head that, under 21 CFR 601.5(b)(1) and (b)(2), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection or the manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection cannot be made, proceedings for license revocation may be instituted. In the same letter, FDA indicated that a meaningful inspection could not be made at the establishment and issued the firm notice of FDA's intent to revoke U.S. License No. 458–001 and announced its intent to offer an opportunity for a hearing.

Because FDA has made reasonable efforts to notify the firm of the proposed revocation and no response was received from the firm, FDA is proceeding under 21 CFR 12.21(b) and publishing this notice of opportunity for a hearing on a proposal to revoke the licenses of the above establishment.

FDA has placed copies of the documents relevant to the proposed revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. These documents include the following: (1) FDA letters to the Responsible Head dated November 14, 1996, and January 24, 1997; and (2) memorandum regarding the investigation and inspection dated December 9, 1996. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Knickerbocker Biologicals, Inc., may submit a written request for a hearing to the Dockets Management Branch by November 5, 1997, and any data and information justifying a hearing must be submitted by December 5, 1997. Other interested persons may submit comments on the proposed license revocation to the Dockets Management Branch by December 5, 1997. The failure of the licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation.

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data to justify a hearing on proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, or if a request for a hearing is not made within the required time with the required format or required analyses, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Such submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502,