Copies of these assurances/certifications are reprinted at the end of this announcement and should be reproduced, as necessary. A duly authorized representative of the applicant organization must certify that the applicant is in compliance with these assurances/certifications. A signature on the SF 424 indicates compliance with the Drug Free Workplace Requirements, and Debarment and Other Responsibilities certifications, and need not be mailed back with the application.

In addition, applicants are required under Section 162(c)(3) of the Act to provide assurances that the human rights of all individuals with developmental disabilities (especially those individuals without familial protection) who will receive services under projects assisted under Part E will be protected consistent with section 110 (relating to the rights of individuals with developmental disabilities). Each application must include a statement providing this assurance.

For research projects in which human subjects may be at risk, a Protection of Human Subjects Assurance may be required. If there is a question regarding the applicability of this assurance, contact the Office for Research Risks of the National Institutes of Health at (301) 496–7041.

E. Checklist for a Complete Application

The checklist below is for your use to ensure that your application package has been properly prepared.—

—One original, signed and dated application, plus two copies. Applications for different Priority Area are packaged separately;
—Applications must specifically identify one Priority Area to compete under on the first page of the application.
—Applications for different Priority Areas must be package and identified separately;
Application is from an organization that is eligible under the eligibility requirements, defined in the Priority Area description;
—Application length does not exceed 60 pages, including attachments and excluding federally required forms.

A complete application consists of the following items in this order:

—Application for Federal Assistance (SF 424, REV 4–88);
—A completed SPOC certification with the date of SPOC contact entered in line 16, page 1 of the SF 424 if applicable.
—Budget Information—Non-Construction Programs (SF 424A, REV 4–88);
—Budget justification for Section B—Budget Categories;
—Table of Contents;
—Letter from the Internal Revenue Service, etc. to prove non-profit status, if necessary;
—Copy of the applicant's approved indirect cost rate agreement, if appropriate;
—Project Description (See Part III, Section C);
—Any appendices/attachments;
—Assurances—Non-Construction Programs (Standard Form 424B, REV 4–88);
—Certification Regarding Lobbying; and
—Certification of Protection of Human Subjects, if necessary.
—Certification of the Pro-Children Act of 1994; signature on the application represents certification.

F. The Application Package

Each application package must include an original and two copies of the complete application. Each copy should be stapled securely (front and back if necessary) in the upper left-hand corner. All pages of the narrative (including charts, tables, maps, exhibits, etc.) must be sequentially numbered, beginning with page one. In order to facilitate handling, please do not use covers, binders or tabs. Do not include extraneous materials as attachments, such as agency promotion brochures, slides, tapes, film clips, minutes of meetings, survey instruments or articles of incorporation.

G. Paper Reduction Act of 1995 (Public Law 104–13)

The Uniform Project Description information collection within this announcement is approved under the Uniform Project Description (0970–0139), Expiration Date 12/31/2003.

Public reporting burden for this collection of information is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information.

Any federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

(Federal Catalog of Domestic Assistance Number 93.631 Developmental Disabilities—Projects of National Significance)

Dated: May 23, 2002.

Patricia Morrissey,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 02–13427 Filed 5–29–02; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0052]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Temporary Marketing Permit Applications

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 July 1, 2002.

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: Stuart Shapiro, 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.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i) (OMB Control Number 0910–0133)—Extension

Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food ''[w]henever * * * such action will promote honesty and fair dealing in the interest of consumers * * *.'' Under section 403(g) of the act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate

commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) specifies the information that a firm must submit to FDA to obtain a temporary marketing permit. The information required in a temporary marketing permit application under §130.17(c) enables the agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions of standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
130.17(c)	7	1	7	25	175
130.17(i)	4	2	8	2	16
Total					191

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

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received October 1, 1998, through September 30, 2001, and information from firms that have submitted recent requests for temporary marketing permits.

Dated: May 23, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–13589 Filed 5–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0215]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export of FDA Regulated Products—Export Certificates

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 the proposed information collection requirements imposed on firms that intend to export to countries that require an export certificate as a condition of entry for FDA regulated products.

DATES: Submit written or electronic comments on the collection of information by July 29, 2002.

ADDRESSES: Submit 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: Mark L. Pincus, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

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 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.

Requesting Export Certificates for FDA Regulated Products under U.S.C. Sections 801(e) and 802—New Collection

FDA is requesting approval from the Office of Management and Budget (OMB) for the collection of information from the public associated with the export of FDA-regulated products as indicated in sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e) and 382), as amended.

In April 1996, a new law entitled ''The FDA Export Reform and Enhancement Act of 1996'' was enacted. It was designed to ease restrictions on exportation of unapproved products regulated by FDA and to facilitate such exportation by provide foreign governments certificates verifying that the products may be legally exported. Specifically, section 801(e)(4) of the act provides that persons exporting certain FDA-regulated products may request that FDA certify that the products meet the requirements of section 801(e) or