SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

FD&C Act Section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
502(u)	10	100	1,000	0.1	100

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

The requirements of section 502(u) of the FD&C Act impose a minimal burden on industry. This section of the FD&C Act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket submission database, FDA estimates that there are 10 establishments that distribute approximately 1,000 reprocessed SUDs. Each response is anticipated to take 0.1 hours resulting in a total burden to industry of 100 hours.

Dated: September 22, 2011.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2011–24788 Filed 9–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0108]

Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.'' This guidance provides recommendations to applicants considering whether to request a waiver or reduction in user fees. This guidance is a revision of the draft guidance entitled ''Draft Interim Guidance Document for Waivers of and Reductions in User Fees,'' issued July 16, 1993.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on this guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Michael Jones, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6216, Silver Spring, MD 20993–0002, 301–796–3602; or
Stephen Ripley, Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.'' This guidance provides recommendations for applicants planning to request waivers or reductions in user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379g and 379h, respectively). This guidance describes the types of waivers and reductions permitted under the user fee provisions of the FD&C Act and the procedures for submitting requests for waivers or reductions and requests for reconsideration and appeal. The guidance also provides clarification on related issues such as user fee exemptions for orphan drugs.

In the **Federal Register** of March 14, 2011 (76 FR 13629), FDA announced the availability of a revised draft guidance entitled ''User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.'' The notice gave interested persons the opportunity to comment by June 13, 2011. We received no comments on the revised draft guidance; however, we have made minor editorial changes and a small clarification to the guidance document.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on user fee waivers and reductions for drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0639. The guidance also refers to collections of information for filling out and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet), previously approved under OMB control number 0910–0297, and collections of information associated with new drug applications or biologics license applications approved under OMB control numbers 0910–0001 and 0910–0338, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*, or at *http://www.regulations.gov.*

Dated: September 21, 2001.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24739 Filed 9–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Healthy Communities Study: How Communities Shape Children's Health (HCS)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 17, 2011, Pages 35452–3 and allowed 60 days for public comment. Three (3) comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Healthy Communities Study: How Communities Shape Children's Health (HCS). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The HCS will address the need for a cross-cutting national study of community programs and policies and their relationship to childhood obesity. The HCS is an observational study of communities conducted over five years that aims to (1) Determine the associations between community programs/policies and Body Mass Index (BMI), diet, and physical activity in children; and (2) identify the community, family, and child factors that modify or mediate the associations between community programs/policies and BMI, diet, and physical activity in children. A total of 279 communities and over 23,000 children and their parents will be part of the HCS over the five-year study. A HCS community is defined as a high school catchment area and the age range of children is 3–15 years upon entry into the study. The study examines quantitative and qualitative information obtained from community-based initiatives; community characteristics (*e.g.,* school environment); measurements of children's physical activity levels and dietary practices; and children's and parents' BMIs. Results from the Healthy Communities Study may influence the future development and funding of policies and programs to reduce childhood obesity. Furthermore, HCS results will be published in scientific journals and will be used for the development of future research initiatives targeting childhood obesity. *Frequency of Response:* Varies by participant type from once to 2.74 times. *Affected Public:* Families or households; businesses, other for-profit, and non-profit. *Type of Respondents:* Parents, children, community key informants (who have knowledge about community programs/policies related to healthy nutrition, physical activity, and healthy weight of children), food service personnel, physical education instructors, state health department employees, and physicians or medical secretaries. The annual reporting burden is as follows: *Estimated number of respondents:* 247,619; *Estimated Number of Responses per Respondent:* 1.1; *Average (Annual) Burden Hours per Response:* 0.12; and *Estimated Total Burden Hours Requested:* 33,144. The annualized cost to respondents is estimated at $434,789. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents *	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested *
Parents/Caregivers (screening)	169,650	1	0.17	9,614
Parents/Caregivers	20,358	1.46	1.14	11,295
Second Parents/Caregivers	10,179	1	0.12	407
Parents/Caregivers who refuse to participate	2,410	1	0.17	137
Children	20,358	1.46	0.78	7,728
Key Informants (screening)	4,820	1	0.08	129
Key Informants	3,615	2.74	0.85	2,806
Food Service Personnel	964	1	0.42	135
Physical Education Instructors	964	1	0.25	80
State Health Department employees	50	1	0.30	5
Physicians/medical secretaries	14,251	1	0.17	808
Total	247,619	.....	.....	33,144

* Estimated for first three years of the five-year study.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have