DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2875]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Blood Establishment Registration and Product Listing, Form FDA 2830

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 January 19, 2000.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Blood Establishment Registration and Product Listing, Form FDA 2830—21 CFR Part 607 (OMB Control Number 0910–0052)—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or device must register with the Secretary of Health and Human Services, by December 31 of each year, his or her name, place of business and all such establishments, and submit, among other information, a listing of all drug or device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products. Section 607.20(a) requires certain establishments that engage in the manufacture of blood products to register and to submit a list of blood products in commercial distribution. Section 607.21 requires the establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a blood product listing at that time. In addition, establishments are required to register annually between November 15 and December 31 and update their blood product listing every June and December. Section 607.22 requires the use of Form FDA 2830, Blood Establishment Registration and Product Listing, for registration and blood product listing. Section 607.25 indicates the information required for establishment registration and blood product listing. Section 607.26 requires for certain changes an amendment to the establishment registration to be made within 5 days of such changes. Section 607.30 requires establishments to update, as needed, their blood product listing information every June and at the annual registration. Section 607.31 requires that additional blood product listing information be provided upon FDA request.

Among other uses, this information assists FDA in its inspections of facilities, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the nation's blood supply. Form FDA 2830 is used to collect this information. The likely respondents are blood banks, blood collection facilities, and blood component manufacturing facilities.

FDA estimates the burden of this collection of information based upon the past experience of the Center for Biologics Evaluation and Research, Division of Blood Applications in regulatory blood establishment registration and product listing. Most blood banks are familiar with the regulations and registration requirements to fill out this form.

In the **Federal Register** of September 3, 1999 (64 FR 48408), the agency requested comments on the proposed collection of information. No significant comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Sections	Form FDA 2830	No. of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
607.20(a), 607.21, 607.22, and 607.25	Initial Registration	300	1	300	1	300
607.21, 607.22, 607.25, 607.26, and 607.31	Re-registration	3,300	1	3,300	0.5	1,650
607.21, 607.25, 607.30, and 607.31	Product Listing Update	75	1	75	0.25	19
Total						1,969

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

Dated: December 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–3089]

Affirmative Agenda for International Activities—Center for Food Safety and Applied Nutrition, Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the Center for Food Safety and Applied Nutrition's (CFSAN) Affirmative Agenda for International Activities (International Affirmative Agenda). CFSAN intends to use the general framework of 2000 to 2002 priorities identified in the International Affirmative Agenda during its annual planning process to develop specific international activities for each of the 3 years.

ADDRESSES: The International Affirmative Agenda is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.1601, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John W. Jones, Office of Constituent Operations, Center for Food Safety and Applied Nutrition (HFS–550), 200 C St. SW., Washington, DC 20204, 202–205–4311.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 17, 1999 (64 FR 50518), FDA announced the availability of CFSAN's Draft International Affirmative Agenda for 2000 to 2002. FDA also solicited comments on whether to hold a public meeting on the Draft International Affirmative Agenda. Interested persons were given until October 1, 1999, to request a public meeting and until November 1, 1999, to comment. The current notice summarizes the comments received on the draft document and announces the availability of the final version of CFSAN's International Affirmative Agenda. CFSAN intends to use the general framework of 2000 to 2002 priorities identified in the International Affirmative Agenda during the center's annual planning process to develop specific international activities. CFSAN also intends to solicit public input on these planned international activities on an annual basis. Therefore, there will be continuing opportunity for public comment on CFSAN's planned international activities and on the center's overall international priorities.

II. Summary of Comments

FDA received eight letters, each containing one or more comments, on CFSAN's Draft International Affirmative Agenda from a consumer group, a food and drug professional association, and six industry trade associations. FDA received only one request for a public meeting and, based on this, the agency determined that there was not sufficient interest to conduct such a meeting. All of the substantive comments strongly supported the goals of CFSAN's Draft International Affirmative Agenda for 2000 to 2002. The comments articulated some concerns and made a number of suggestions.

A number of comments were related to FDA's public health mandate, the need for FDA to ensure that this mandate is not compromised by trade concerns, and the suggested need for FDA to promote proactively U.S. public health positions in deliberations of international standard setting bodies.

Most, but not all, of these comments suggested that CFSAN only participate in international activities that are consistent with and directly responsive to FDA's mission to protect the public health that is mandated explicitly by statute. Concern was expressed about possible CFSAN activities that appear to promote a particular technology (e.g., biotechnology) or that pertain to equivalence or mutual recognition agreements where, it was asserted, FDA's ability to protect public health would be lowered. There was also concern about any CFSAN activity related to the World Trade Organization (WTO) or North American Free Trade Agreement (NAFTA) that is undertaken explicitly to promote international trade at the expense of public health. The suggestion also was made that CFSAN should oppose actively the establishment of any standard by the Codex Alimentarius Commission (Codex) that does not provide a level of consumer protection equivalent to that which is provided by FDA regulation. One comment, however, suggested that FDA should undertake international activities specifically to support U.S. economic, trade, and market development interests overseas.

Some comments recommended that CFSAN strengthen its participation in Codex to ensure that Codex standards are based on sound scientific principles. These comments emphasized that CFSAN should work closely with the appropriate food industry representatives to develop technically accurate U.S. positions on matters before Codex and to ensure that Codex standards are practicable. The comments also suggested that CFSAN's participation in the Codex development process should be an agency priority and its delegates should be appropriately trained to strengthen the agency's participation.

Likewise, comments suggested that CFSAN take a more proactive and leadership role in developing appropriate work plans for the technical working groups (TWG's) convened under the NAFTA Sanitary and Phytosanitary (SPS) committee, particularly in the area of harmonized regulation procedures for food additives, safety assessments for foods derived from biotechnology, product recall and traceback procedures, and harmonized NAFTA positions on issues before Codex. The agency also was encouraged to be more actively involved in articulating the strength of the U.S. food regulatory system within the WTO's SPS committee.

FDA intends that all of CFSAN's international activities have as their basis maintenance and enhancement of U.S. public health. The draft International Affirmative Agenda states that consistency with FDA's primary public health mission is the first guiding principle of CFSAN's participation in any international activity. In this regard, CFSAN intends to participate in international activities that are intended, directly or indirectly, to enhance the safety, nutritional quality and informative and truthful labeling of foods, and the safety and labeling of cosmetics available to the American consumer, whether the products are produced in or imported into the United States. CFSAN also intends to participate, when practicable, in activities that address other compelling international or domestic public health issues, concerns or priorities identified by the Department of Health and Human Services and other domestic and foreign public health agencies that are important to CFSAN's areas of expertise and authority.

FDA emphasizes that CFSAN's international activities, including participation in committees of the Codex and other standard setting bodies, are aimed primarily at enhancing the agency's ability to protect