and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 days after the meeting at a cost of 10 cents per page. You may also examine the transcript Monday through Friday between 9 a.m. and 4 p.m. in the Dockets Management Branch or on the Internet at *http://www.fda.gov/ohrms/dockets/dockets/dockets.htm* (select docket # 03N–0168). The transcript will be available 4–6 weeks after the meeting.

V. Electronic Access

Persons with access to the Internet may obtain a copy of the commissioned study report at *http://www.fda.gov/cder/reports/prescriptioninfo/default.htm*, the Action Plan at *http://www.keystone.org,* and a transcript of FDA's July 17, 2002, Drug Safety and Risk Management Advisory Committee meeting at *http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3874T1.htm*.

Dated: May 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14212 Filed 6–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0359]

Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2004. As part of its annual planning, budgeting, and resource allocation process, CFSAN is reviewing its programs to set priorities and establish work product expectations. This notice is being published to give the public an opportunity to provide input into the priority-setting process.

DATES: Submit written or electronic comments by August 4, 2003.

ADDRESSES: Submit written comments concerning this document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Donald J. Carrington, Center for Food Safety and Applied Nutrition (HFS–666), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1697, or e-mail: *Dcarring@cfsan.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 10, 2003, CFSAN released a document entitled ''2003 CFSAN Program Priorities.'' The document, a copy of which is available on CFSAN's Web site (*www.cfsan.fda.gov*), constitutes the center's priority work plan for FY 2003, i.e., October 1, 2002, through September 30, 2003. (Copies also are available from the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section.) The 2003 work plan is based on input we received from our stakeholders as well as input generated internally. Throughout the priority-setting process, we focus on one central question: ''Where do we do the most good for consumers?''

The FY 2003 work plan focuses heavily on ensuring the security of our country's food supply as a primary goal. With the enactment in June 2002 of the Public Health Security and Bioterrorism Preparedness and Response Act (Public Law 107–188), much of our effort during the current fiscal year will focus on issuing the necessary regulations to implement this statute. We will also continue to enhance our level of emergency preparedness, particularly our laboratory preparedness.

The FY 2003 work plan continues to place a high priority on food safety, food additives, and dietary supplements, and also highlights our desire to revitalize our nutrition program. In December 2002, FDA announced a major initiative to enhance ''Consumer Health Information for Better Nutrition.'' Accordingly, this year's plan includes the steps needed to implement that initiative, including increased enforcement against unsubstantiated claims on food and dietary supplement products.

Outside of these priorities, the FY 2003 work plan identifies eight other program areas and cross-cutting areas that need emphasis: (1) Cosmetics; (2) enhancing the science base; (3) international activities; (4) food biotechnology; (5) enhancing internal processes; (6) focused economic-based regulations; (7) equal employment opportunity/diversity initiatives; and (8) management initiatives.

The FY 2003 work plan contains two lists of activities—the ''A-list'' and the ''B-list.'' Our goal is to fully complete at least 90 percent of the 145 ''A-list'' activities by the end of the fiscal year, September 30, 2003. Activities on the ''B-list'' are those we plan to make progress on, but may not complete, before the end of the fiscal year.

CFSAN intends to issue a mid-year progress report on what program priority activities already have been completed to date in FY 2003 as well as any adjustments in the work plan (i.e., additions or deletions) for the balance of the fiscal year.

CFSAN has responsibility for many important ongoing activities that are not identified in the work plan. For example, the center's base programs in data collection, research, and enforcement are important and ongoing. Rather, the work plan addresses primarily those initiatives representing something new or different that we need to address in 2003 as well as priority initiatives that are being continued from the 2002 work plan. In addition, the work plan does not address the myriad of unanticipated issues that often require a substantial investment of CFSAN resources (e.g., response to outbreaks of foodborne illness).

II. 2004 CFSAN Program Priorities

FDA is requesting comments concerning the establishment of program priorities in CFSAN for FY 2004, and the input will be used to develop CFSAN's 2004, work plan. The work plan will set forth the center's program priorities for October 1, 2003, through September 30, 2004. FDA intends to make the 2004 work plan available in the fall of 2003.

The format of the 2004 work plan will be similar to last year's work plan. FDA expects there will be considerable continuity and followthrough between the 2003 and 2004 work plans. For example, new initiatives aimed at increasing the security of our country's food supply and revitalizing our nutrition program will continue to be a high priority in FY 2004.

FDA is in the process of developing a major strategic plan and has identified the following five top priority areas for the agency: (1) A strong FDA; (2) efficient risk management; (3) patient and consumer safety; (4) better informed consumers; and (5) counter-terrorism. Action items implementing the strategic plan will be incorporated into CFSAN's priorities for FY 2004.

As noted in the previous paragraphs, many of the ''B-list'' activities are 2-year projects that we are positioning to be candidates for the ''A-list'' next year.

FDA requests comments on which ''B-list'' activities should be elevated to the ''A-list'' for completion in 2004. Finally, as noted, FDA requests comments on new program areas or activities that should be added as a high priority for FY 2004.

III. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14106 Filed 6–4–03; 8:45 am]

BILLING CODE 4106–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Drug Pricing Program Reporting Requirements (OMB No. 0915–0176)—Revision

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(5)(C) to develop audit guidelines and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Pharmacy Affairs Branch (PAB) has developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

Audit Guidelines

A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of section 340B. If the problem cannot be resolved, the manufacturer must then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to the HRSA PAB for review. The office will review the documentation to determine if reasonable cause exist. Once the audit is completed, the manufacturer will submit copies of the audit report to the HRSA PAB for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General.

Dispute Resolution Guidelines

Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA PAB has developed an informal dispute resolution process which can be used if an entity or manufacturer is believed to be in violation of section 340B. Prior to filing a request for resolution of a dispute with the HRSA PAB, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to the HRSA PAB. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

To date, there have been no requests for audits, but two disputes have reached the level where a committee review may be needed. As a result, the estimates of annualized hour burden for audits and disputes have been reduced to the level shown in the table below.

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/ response	Total burden hours
AUDITS					
Audit Notification of Entity [1]	2	1	2	4	8
Audit Workplan [1]	1	1	1	8	8
Audit Report [1]	1	1	1	1	1