Treatment for Faith-based Organizations, which includes the prohibition against Federal funding of inherently religious activities, can be found at either 45 CFR 87.1 or the HHS web site at *http://www.os.dhhs.gov/fbci/waisgate21.pdf.*

45 CFR Part 74

45 CFR Part 92

Grantees are subject to the requirements in 45 CFR Part 74 (non-governmental) or 45 CFR Part 92 (governmental) organizations.

Grantees may be asked to participate in a national evaluation of the Community-Based Abstinence Education program. The grantee will cooperate with any research or evaluation efforts sponsored by the Administration for Children and Families (ACF).

3. Reporting Requirements

All grantees are required to submit semi-annual (quarterly or annual) program reports; grantees are also required to submit semi-annual expenditure reports using the required financial standard form (SF–269) which can be found at the following URL: *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

Final reports are due 90 days after the end of the grant period.

Programmatic Reports: Semi-Annually.

Financial Reports: Semi-Annually.

VII. Agency Contacts

Program Office Contact

Jeffrey Trimbath, Family and Youth Services Bureau, 118 Q Street, NW., Washington, DC 20002–2132. Phone: 1–866–796–1591. E-mail: *fysb@dixongroup.com.*

Grants Management Office Contact

Peter Thompson, Grants Officer, ACYF Grants Office, 118 Q Street, NW., Washington, DC 20002–2132. Phone: 1–866–796–1591. E-mail: *fysb@dixongroup.com.*

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *http://www.Grants.gov.* Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html.*

Applicants will be sent acknowledgements of received applications.

Dated: May 16, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

Appendix A—Section 510 of Title V of the Social Security Act

SEC. 510. [42 U.S.C. 710] (a) For the purpose described in subsection (b), the Secretary shall, for fiscal year 1998 and each subsequent fiscal year, allot to each State which has transmitted an application for the fiscal year under section 505(a) an amount equal to the product of:

(1) The amount appropriated in subsection (d) for the fiscal year; and

(2) The percentage determined for the State under section 502(c)(1)(B)(ii).

(b)(1) The purpose of an allotment under subsection (a) to a State is to enable the State to provide abstinence education, and at the option of the State, where appropriate, mentoring, counseling, and adult supervision to promote abstinence from sexual activity, with a focus on those groups which are most likely to bear children out-of-wedlock.

(2) For purposes of this section, the term ''Abstinence Education'' means an educational or motivational program which:

(A) Has as its exclusive purpose, teaching the social, psychological, and health gains to be realized by abstaining from sexual activity;

(B) Teaches abstinence from sexual activity outside marriage as the expected standard for all school age children;

(C) Teaches that abstinence from sexual activity is the only certain way to avoid out-of-wedlock pregnancy, sexually transmitted diseases, and other associated health problems;

(D) Teaches that a mutually faithful monogamous relationship in the context of marriage is the expected standard of human sexual activity;

(E) Teaches that sexual activity outside of the context of marriage is likely to have harmful psychological and physical effects;

(F) Teaches that bearing children out-of-wedlock is likely to have harmful consequences for the child, the child's parents, and society;

(G) Teaches young people how to reject sexual advances and how alcohol and drug use increases vulnerability to sexual advances; and

(H) The importance of attaining self-sufficiency before engaging in sexual activity.

(c)(1) Sections 503, 507, and 508 apply to allotments under subsection (a) to the same extent and in the same manner as such sections apply to allotments under section 502(c).

(2) Sections 505 and 506 apply to allotments under subsection (a) to the extent determined by the Secretary to be appropriate.

(d) For the purpose of allotments under subsection (a), there is appropriated, out of any money in the Treasury not otherwise appropriated, an additional $50,000,000 for each of the fiscal years 1998 through 2002.

The appropriation under the preceding sentence for a fiscal year is made on October 1 of the fiscal year.

Appendix B—Voluntary Assurance

As the authorized individual signing this grant application on behalf of (name of applicant), I hereby attest and certify that (name of applicant organization), while administering Federal and/or non-Federal funds under the Community-Based Abstinence Education Program, will not provide to an adolescent and/or adolescents any other education regarding sexual conduct, except that, in the case of an entity expressly required by law to provide health information or services. In this circumstance, health information or services (expressly required by law) must be conducted in a different setting—either in time or place—than where and when the abstinence-only course is being conducted.

Date

Printed Name of Authorized Individual

Signature of Authorized Individual

[FR Doc. 05–10105 Filed 5–19–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998N–0359 (formerly 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) 2006. 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 July 19, 2005.

ADDRESSES: Submit written comments concerning this document to the Division of Dockets Management (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 December 1, 2004, CFSAN released a document entitled ''FY 2005 CFSAN Program Priorities.'' The document, a copy of which is available on CFSAN's Web site (*www.cfsan.fda.gov*) or from the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section, constitutes the Center's priority workplan for FY 2005 (i.e., October 1, 2004, through September 30, 2005). The FY 2005 workplan is based on input we received from our stakeholders (see 69 FR 35380, June 24, 2004), as well as input generated internally. The primary focus is: ''Where do we do the most good for consumers?''

The FY 2005 workplan contained three lists of activities, as follows: The ''A-list,'' the ''B-list,'' and a ''Priority Ongoing Activities'' list. Our goal is to complete fully at least 90 percent of the ''A-list'' activities by the end of the fiscal year, September 30, 2005. Activities on the ''B-list'' are those we plan to make progress on, but may not complete before the end of the fiscal year. Items in the ''Priority Ongoing Activities'' list illustrate some of the many priority activities the Center performs on a regular basis in addition to those identified on our ''A'' and ''B'' lists.

CFSAN intends to issue a progress report on what program priority activities already have been completed to date in the summer of FY 2005, as well as any adjustments in the workplan (i.e., additions or deletions) for the balance of the fiscal year.

II. 2006 CFSAN Program Priorities

FDA is requesting comments on what program priorities CFSAN should consider establishing for FY 2006. The input will be used to develop CFSAN's FY 2006 workplan. The workplan will set forth the Center's program priorities for the period of October 1, 2005, through September 30, 2006. FDA intends to make the FY 2006 workplan available in the fall of 2005.

The format of the FY 2006 workplan will be identical to the FY 2005 plan, and it will be formatted into the following five sections:

(1) Ensuring Food Defense and Security,

(2) Improving Nutrition and Dietary Supplement Safety,

(3) Ensuring Food/Color Additives and Cosmetic Safety,

(4) Ensuring Food Safety: Crosscutting Areas, and

(5) Priority Ongoing Activities.

FDA expects there will be considerable continuity and followthrough between the 2005 and 2006 workplans. For example, initiatives aimed at increasing the security of our country's food supply will continue to be a high priority in FY 2006. FDA requests comments on other broad program areas that should continue to be a priority, as well as new program areas or activities that should be added as a high priority, for FY 2006.

III. Comments

Interested persons may submit to the Division of Dockets Management (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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–10033 Filed 5–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket 2004P–0220]

Determination That ZITHROMAX (Azithromycin) 250-Milligram Oral Capsules Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ZITHROMAX (azithromycin) 250-milligram (mg) oral capsules were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for azithromycin 250-mg oral capsules.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ZITHROMAX (azithromycin) 250-mg oral capsules are the subject of NDA 50–670 held by Pfizer, Inc. (Pfizer). FDA approved NDA 50–670 on November 1, 1991. In February 1994, Pfizer submitted NDA 50–711 for ZITHROMAX (azithromycin) 250-mg tablets. Pfizer explained that the new dosage form was intended to replace the capsule formulation. Pfizer decided to change the dosage form from capsules to tablets because tablets do not have a