

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 201, 208, and 209**

[Docket No. 2003N-0342]

Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products; Correction**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of April 22, 2004 (69 FR 21778). The document proposed to amend the agency's regulations governing the format and content of labeling for human drug products for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355). The document published with inadvertent errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 04-9069, appearing on pages 21778 and 21779 in the **Federal Register** of Thursday, April 22, 2004, the following corrections are made:

1. On page 21778, in the third column, in the heading of the document, "[Docket No. 2003N-0324]" is corrected to read [Docket No. 2003N-0342].

2. On page 21778, in the third column, in the **ADDRESSES** section, in the second line beginning with "identified by", "Docket No. 2003N-0324" is corrected to read "Docket No. 2003N-0342".

3. On page 21779, in the first column, in the **ADDRESSES** section, in the ninth line beginning with "Docket No. 2003N-0324", "Docket No. 2003N-0324" is corrected to read "Docket No. 2003N-0342".

Dated: June 1, 2004.

Jeffrey Shuren,*Assistant Commissioner for Policy.*

[FR Doc. 04-12841 Filed 6-4-04; 8:45 am]

BILLING CODE 4160-01-S**AGENCY FOR INTERNATIONAL DEVELOPMENT****22 CFR Parts 202, 205, 211, and 226**

RIN 0412-AA52

Participation by Religious Organizations in USAID Programs**AGENCY:** Agency for International Development (USAID).**ACTION:** Proposed rule.

SUMMARY: This rule proposes to implement Executive Branch policy that, within the framework of constitutional guidelines, religious (or "faith-based") organizations should be able to compete on an equal footing with other organizations for USAID funding. This proposed rule would revise USAID regulations pertaining to the award of grants, cooperative agreements and contracts awarded for the purpose of administering grant programs to ensure their compliance with this policy and to clarify that faith-based organizations are eligible to participate in programs on the same basis as any other organization, with respect to programs for which such other organizations are eligible.

DATES: Comments must be submitted by August 6, 2004.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the: Center for Faith-Based and Community Initiatives, U.S. Agency for International Development, Room 3.09-22, 1300 Pennsylvania Avenue, NW., Washington, DC 20523. Communications should refer to the "proposed rule." You may submit your comments by fax to 202-216-3351 or by e-mail to fbc@usaid.gov. A copy of each communication submitted will be available for inspection and copying between 8:30 a.m. and 5:30 p.m. at the above address.

FOR FURTHER INFORMATION CONTACT: Michael Magan, Director, Center for Faith-Based and Community Initiatives, USAID, Rm. 3.3.30, 1300 Pennsylvania Ave., NW., Washington, DC 20523; telephone: (202) 712-4080 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:**I. Background**

Religious (or "faith-based") organizations make an important contribution to the delivery of humanitarian and economic assistance in much of the world. Faith-based organizations acting alone or in partnership with local and national governments, community-based

organizations, institutions of higher education, and other private organizations do much good work to meet the pressing needs of countries and their citizens, consistent with the objectives of the U.S. foreign assistance program.

Faith-based non-profit organizations have been implementing humanitarian and development activities for USAID for decades. Nevertheless, USAID seeks to further facilitate the contribution of faith-based and community organizations to increase the reach and effectiveness of its programs. We believe this will strengthen the effort, given priority in the national security strategy of the United States, to respond to the humanitarian and economic development needs of countries worldwide.

President Bush has directed Federal agencies, including USAID, to take steps to ensure that Federal policy and programs are fully open to faith-based and community groups in a manner that is consistent with the Constitution. The Administration believes that such groups possess an under-appreciated ability to meet the needs of disadvantaged people overseas struggling to make a better life, recover from a disaster or live in a free and democratic country. The Administration believes that there should be an equal opportunity for *all* organizations—both religious and nonreligious—to participate as partners in Federal programs.

As part of these efforts, President Bush issued Executive Order 13198 on January 29, 2001. The Order, which was published in the **Federal Register** on January 31, 2001 (66 FR 8499), created Centers for Faith-Based and Community Initiatives in five Cabinet departments—Housing and Urban Development, Health and Human Services, Education, Labor, and Justice. The Executive Order charged the Centers to identify and eliminate regulatory, contracting, and other programmatic obstacles to the participation of faith-based and community organizations in the provision of social services by their Departments. On December 12, 2002, President Bush issued Executive Order 13280. That Order, published in the **Federal Register** on December 16, 2002 (66 FR 77145), created Centers in two additional agencies—the United States Agency for International Development and the Department of Agriculture—and charged those Centers with duties similar to those set forth in Executive Order 13198. On December 12, 2002, President Bush also issued Executive Order 13279, published in the **Federal Register** on December 12, 2002 (67 FR