

disregards income of a stepparent whose needs are not included in the assistance unit for the first 6-months of receipt of public assistance; excludes summer earnings of teens and interest income; lowers age of child for JOBS exemption to 6-months; raises asset limit to \$5,000 plus a vehicle of reasonable worth used primarily for self-sufficiency purposes; extends transitional Medicaid and child care benefits; eliminates 100-hour and required quarters of work rules, and (on a case-by-case basis) the 6-month time limit requirements in the AFDC-UP program; requires school conferences and regular school attendance; offers incentive payments to private employers who hire hard-to-place AFDC recipients; and allows non-custodial parents of AFDC children to participate in JOBS. Statewide, the demonstration requires immunizations of pre-school-age children.

*Dated Received:* 8/2/95.

*Type:* Combined AFDC/Medicaid.

*Current Status:* New.

*Contact Person:* Don Winstead, (904) 921-5567.

### III. Requests for Copies of a Proposal

Requests for copies of this proposal should be directed to the Administration for Children and Families (ACF) at the address listed above. Questions concerning the content of the proposal should be directed to the State contact listed for the proposal.

(Catalog of Federal Domestic Assistance Program, No. 93562; Assistance Payments—Research).

*Dated:* August 11, 1995.

#### Howard Rolston,

*Director, Office of Policy and Evaluation.*

[FR Doc. 95-20293 Filed 8-15-95; 8:45 am]

BILLING CODE 4184-01-P

### Food and Drug Administration

[Docket No. 95M-0119]

#### Chartex International plc; Premarket Approval of Femidom® Female Condom; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 8, 1995 (60 FR 30310). The document announced the approval of the premarket approval application for the Femidom® Female Condom. The document was published with some errors. This document corrects those errors.

**FOR FURTHER INFORMATION CONTACT:** Marquita B. Steadman, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4765.

In FR Doc. 95-14059, appearing on page 30310 in the **Federal Register** of Thursday, June 8, 1995, the following corrections are made: On page 30310, in the second column, under the **SUMMARY** caption, in the fourth line, and under the **SUPPLEMENTARY INFORMATION** caption, in the second line, insert "Rhys, Bryant, U.S. representative for" before "Chartex International plc, London, U. K.,".

*Dated:* August 8, 1995.

#### Joseph A. Levitt,

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 95-20313 Filed 8-15-95; 8:45 am]

BILLING CODE 4160-01-F

#### Medical Devices; Mammography Facilities Education and Training; Notice of Public Workshops

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshops.

**SUMMARY:** The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Office of External Affairs, and Center for Devices and Radiological Health) is sponsoring five grassroots workshops on FDA requirements for compliance with the Mammography Quality Standards Act of 1992 (the MQSA). These workshops are designed to assist mammography facilities in complying with the regulations that went into effect on October 1, 1994.

**DATES:** The public workshops are scheduled as follows:

1. Thursday, August 17, 1995, 8 a.m. to 4:30 p.m., Dallas, TX.
2. Thursday, August 24, 1995, 8 a.m. to 4:30 p.m., Charlotte, NC.
3. Wednesday, September 6, 1995, 8 a.m. to 4:30 p.m., Fort Mitchell, KY.
4. Thursday, September 21, 1995, 8 a.m. to 4:30 p.m., San Juan, PR.
5. Thursday, September 28, 1995, 8 a.m. to 4:30 p.m., Los Angeles, CA.

**ADDRESSES:** The public workshops will be held at the following locations:

1. Dallas—Harvey Hotel, 400 North Olive, Dallas, TX.
2. Charlotte—New Charlotte Convention Center, 501 South College St., Charlotte, NC.
3. Fort Mitchell—Drawbridge Estates, 2477 Royal Dr., Fort Mitchell, KY.

4. Puerto Rico—Radisson Normandie Hotel, Avenida Munoz Rivera, Esquina Rosales, San Juan, PR.

5. Los Angeles—Continental Plaza, Los Angeles Airport, 9750 Airport Blvd., Los Angeles, CA. (PLEASE NOTE: Location changed since July 19, 1995, "Dear Colleague letter.")

#### FOR FURTHER INFORMATION CONTACT:

Regarding registration for the Dallas public workshop: Belinda Collins, Food and Drug Administration, Southwest Region, 7920 Elmbrook Rd., Dallas, TX 75247-4982, 214-655-8100, ext. 148 or FAX 214-655-8103.

Regarding registration for the Charlotte public workshop: Barbara Ward-Groves, Food and Drug Administration, Southeast Region, 60 Eighth St. SE., Atlanta, GA 30309, 404-347-4001, ext. 5256 or FAX 404-347-4349.

Regarding registration for the Fort Mitchell public workshop: Pat Wolfzorn, Food and Drug Administration, Mid-Atlantic Region, 1141 Central Pkwy., Cincinnati, OH 45202-1097, 513-684-3501, ext. 102 or FAX 513-684-2905.

Regarding registration for the San Juan public workshop: Nilda E. Villegas, Food and Drug Administration, Southeast Region, P. O. Box 5719, Puerta de Tierra Station, 809-729-6852 or FAX 809-729-6847.

Regarding registration for the Los Angeles public workshop: Mark Roh, Food and Drug Administration, Pacific Region, Oakland Federal Bldg., 1301 Clay St., suite 1180-N, Oakland, CA 94612-5217, 510-637-3980 or FAX 510-637-3977.

Those persons interested in attending a workshop should register by FAXING their name, firm name, address, and telephone number to the information contact person listed above for their region. There is no registration fee for these workshops, but advance registration is required. Interested parties are encouraged to register early because space is limited.

**SUPPLEMENTARY INFORMATION:** FDA will conduct training for mammography facilities designed to assist those facilities in complying with the requirements of the MQSA. Those requirements went into effect October 1, 1994. Emphasis will be placed on educational requirements, training, and providing assistance to small business in meeting the MQSA requirements. These meetings are being held, in part, as a response to the National

Performance Review initiative implementing the President's Grassroots Regulatory Partnership Meetings. These workshops are made possible by funding from the Office of Women's Health.

Dated: August 14, 1995.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

[FR Doc. 95-20374 Filed 8-14-95; 12:11 pm]

BILLING CODE 4160-01-F

[Docket No. 95N-0259]

### Over-the-Counter Drug Labeling; Public Hearing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public hearing to discuss over-the-counter (OTC) drug labeling issues. The purpose of the hearing is to solicit information and views concerning various aspects of OTC drug labeling design that would improve the communication of information to consumers. The agency is particularly interested in hearing from individuals, industry, consumer groups, health professionals, and researchers with expertise in communicating information to consumers, skills in design, and insight into consumer needs and desires with respect to OTC drug labeling. In addition, the agency is soliciting written comments and/or data on the costs and benefits of an improved labeling format. **DATES:** The public hearing will be held on September 29, 1995, from 8 a.m. to 3 p.m. Mail or FAX notices of participation to be received by FDA by September 15, 1995. The Nonprescription Drugs Advisory Committee will meet from 3 p.m. to 4 p.m., following the public hearing. This meeting will be open to the public. Written comments will be accepted until December 29, 1995.

**ADDRESSES:** The public hearing will be held at the Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD 20857. Submit written notices of participation and comments to the Dockets Management Branch (HFA-305), ATTN: OTC Drug Labeling Hearing, Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or FAX written notices of participation and comments to the Dockets Management Branch, ATTN: OTC Drug Labeling Hearing, 301-594-3215. Two copies of any comments are to be submitted, except

that individuals may submit one copy. Comments are to be identified with Docket No. 95N-0259. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above). Information specified in this notice can be received by calling 301-594-5000 or sending a self-addressed stamped envelope with your request to the contact person listed below.

**FOR FURTHER INFORMATION CONTACT:**

Michael D. Kennedy, Center for Drug Evaluation and Research (HFD-820), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20857, 301-594-1006.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA has the responsibility to help ensure the safety and effectiveness of OTC drug products and to regulate their labels and labeling. The agency is engaged in an ongoing comprehensive review of the thousands of OTC drug products available to consumers without a prescription. As a result of that review, the agency has required, through notice-and-comment rulemaking, specific language to be included in the labeling of many OTC drug products, which describes the uses, directions, warnings, drug interactions, precautions, active ingredients, and other information that a consumer would need to know to use the product safely and effectively.

With escalating health care costs and the OTC availability of more products once obtainable only by prescription, self-medication is on the rise. Consequently, it is increasingly important that consumers read, understand, and behave in accordance with the information on OTC drug labels and labeling.

FDA regulations require that the OTC drug product labeling present and display information in such a manner as to render it "likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use."<sup>1</sup> (21 CFR 330.10(a)(4)(v)). Despite this regulation, many consumers have complained that OTC drug labels are difficult to understand and that the print size is too small. For example, in 1991, FDA received a citizen's petition requesting regulatory standards for the

<sup>1</sup> Consistent with the act, "labeling" refers to "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." (21 U.S.C. 321(m)).

print size and style of OTC drug product labeling. In the **Federal Register** of March 6, 1991 (56 FR 9363), the agency sought comments on this petition and other issues related to label legibility and readability. FDA received many comments criticizing the print size and complexity of current OTC drug labels and labeling.

The Nonprescription Drug Manufacturers Association (NDMA) has developed "Label Readability Guidelines" (NDMA Guidelines) for its members to use for guidance in designing OTC drug labels. These guidelines have served to provide advice on improving the legibility of OTC drug labeling. Copies of the NDMA guidelines are available from FDA by calling or writing the contact person listed above. FDA commends the drug industry for recognizing the need to improve OTC drug labeling features and for initiating voluntary readability guidelines. FDA, however, is firmly committed to further improving OTC drug labels and labeling and making them easier to read and understand. To date, the agency primarily has worked with manufacturers and consumers in this effort. In January 1995, FDA staff served as chairpersons and participated in a workshop with the Drug Information Association to discuss OTC drug labeling. The workshop was attended by consumers, industry, government officials, and academicians. The purpose was to explore perspectives on how to communicate OTC drug information more effectively to consumers through product labeling.

As part of this ongoing effort to improve OTC drug labeling, FDA is examining different formats that could be used to communicate drug information to consumers in a more effective manner. FDA is now also examining the question of whether a standardized format would aid in achieving the goals of improved communication. The Part 15 hearing announced in this notice is intended to seek public comment on various issues specifically related to the format of OTC drug labeling. In order to further understand consumer needs for OTC label design, FDA is also seeking public comments regarding consumer use and behavior related to OTC drug labeling.

The agency also recognizes that the terms and text required on OTC drug labeling could be improved to make the information easier to understand. The agency intends to hold one or more public meetings in the near future to discuss these issues.