

result of a consent order with the Federal Trade Commission. According to the Federal Trade Commission, advertisements for the Duram Mask claimed that the mask would protect you from all significant fire hazards for up to 20 minutes. These hazards included toxic smoke, poisonous fumes, and lethal gases.

The advertisements for the Duram Mask did not make it clear that the mask does not filter carbon monoxide—a lethal gas associated with fires.

We have now agreed not to make any claims about the mask's ability to protect you from fire hazards, unless we have reliable scientific evidence to back up these statements.

We also have learned that these masks are not appropriate for use in U.S. mines.

While the Duram Mask will not protect you from carbon monoxide gas, it will protect you from other potentially lethal gases associated with fire. These gases include hydrogen chloride, hydrogen cyanide, nitrogen dioxide, and sulfur dioxide.

Life Safety Products

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondents Frank A. Latronica, Jr., doing business as Life Safety Products, and Duram Rubber Products.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

This matter concerns claims made by the respondents in their advertising and other promotional materials that the Duram Emergency Escape Mask will absorb or filter out all significant toxic smoke and poisonous fumes and lethal gases associated with fires; will protect the user from all significant hazards associated with toxic smoke, poisonous fumes and lethal gases in fires for up to twenty minutes; and is appropriate for use in mines. The Commission's complaint charges that respondents' claims are false and misleading because the Duram Emergency Escape Mask will not absorb or filter out all significant toxic smoke and poisonous fumes and lethal gases associated with fires because it does not absorb or filter out carbon monoxide, a lethal gas associated with fires; will not protect the user from all significant hazards associated with toxic smoke, poisonous fumes and lethal gases in fires for up to twenty minutes because it does not absorb or filter out carbon monoxide, a lethal gas associated with fires; and it is not appropriate for use in mines because it does not meet the standards developed by the National Institute for Occupational Safety and Health and the United States Bureau of Mines for Respiratory Protective Devices, as set forth in 30 CFR part 11.

The Commission's complaint also charges that the respondents falsely represented that they possessed and relied upon a reasonable basis that substantiated the above claims. The Commission's complaint alleges that this representation is false and misleading because at the time they made these three representations respondents did not possess and rely upon a reasonable basis that substantiated these claims.

The Commission's complaint also alleges that respondents' failure to disclose to consumers that the Duram Emergency Escape Mask does not absorb or filter out carbon monoxide, is a deceptive practice.

Finally, the Commission's complaint charges that in their advertising and other promotional materials respondents represented, directly or by implication, that scientific tests prove that the Duram Emergency Escape Mask filters 94% of the smoke in an environment filled with smoke. The Commission's complaint alleges that this representation is false and misleading because scientific tests do not prove that the Duram Emergency Escape Mask filters 94% of the smoke in an environment filled with smoke.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondents from engaging in similar acts and practices in the future.

Part I of the proposed order prohibits the respondents from representing, directly or by implication in its advertising or labeling for the Duram Emergency Escape Mask, or any substantially similar product, that such product is capable of absorbing, removing, filtering out, or otherwise protecting the user from any hazardous gas or fumes associated with fire and such product can protect the user from any hazards associated with fire unless such representation are true, and respondents possess and rely upon competent and reliable scientific evidence that substantiates them. Part I of the proposed order also prohibits the respondents from representing, directly or by implication in its advertising or labeling for the Duram Emergency Escape Mask, or any substantially similar product, that such product is appropriate for use in mines, unless such representations are true, and respondents possess and rely upon competent and reliable evidence that substantiates them.

Part II of the proposed order requires respondents to include a disclosure in any advertisement or promotional material for the Duram Emergency Escape Mask or any substantially similar product alerts consumers that the mask is incapable of absorbing, removing, filtering or otherwise providing significant protection from carbon monoxide, if the advertisement or promotional material expressly or impliedly represents that the device protects the user from any hazard associated with fire. The proposed order also specifies the size and placement of such a disclosure for print advertisements and the nature and manner of such a disclosure for audio and visual advertisements.

Part III of the proposed order requires respondents to include a disclosure on all

package labels and package inserts for the Duram Emergency Escape Mask or any substantially similar product that alerts consumers that the mask does not filter carbon monoxide, a lethal gas associated with fire. The proposed order also specifies the size of such a disclosure and that it must be in a typeface and color that are clear and prominent.

Part IV of the proposed order prohibits respondents from representing, directly or by implication, that any fire protection or safety related product protects or assists in protecting the user from respiratory hazards associated with fire, explosions, air pollution, chemical exposure or other environments where normal breathing is impaired, unless, at the time of making such representation, respondents possess and rely upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that substantiates the representation.

Part V of the proposed order prohibits respondents from misrepresenting, in any manner, directly or by implication, for any fire protection or safety related product, the existence, contents, validity, results, conclusions or interpretations of any test or study.

Part VI of the proposed order requires respondents to mail to each person who has purchased the Duram Emergency Escape Mask from Life Safety Products, or from any catalog retailer to whom Life Safety Products has sold the Duram Emergency Escape Mask for resale, a notification letter informing the consumer that the Duram Emergency Escape Mask they have purchased does not filter carbon monoxide.

The remaining parts of the proposed consent order require the respondents to maintain materials relied upon in disseminating any representation covered by the order, to distribute copies of the order to certain company officials and employees, to notify the Commission of any changes in the corporate structure of Duram Rubber Products or the employment status of Mr. Frank A. Latronica, Jr., that might affect compliance with the order, and that each respondent file one or more compliance reports.

The purpose of this analysis is to facilitate public comment on the proposed consent order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statewide Immunization Information System Developer's Workshop

The National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Statewide Immunization Information System (SIIS) Developer's Workshop.

Times and Dates: 8:30 a.m.–4 p.m., August 1, 1995; 8:30 a.m.–4 p.m., August 2, 1995; 8:30 a.m.–4 p.m., August 3, 1995.

Place: Omni Hotel at CNN Center, 100 CNN Center, Atlanta, Georgia 30335, telephone 404/659-0000, (Reservations 404/818-4300).

Status: The meeting will be open to the public, attendance limited only by space available. The meeting room will accommodate approximately 280 people.

Purpose: This workshop will focus on technical issues and guidelines related to the SIIS projects, and CDC's role in the SIIS technical support and implementation.

Matters To Be Discussed: Topics to be discussed will include: SIIS architecture and design; Record Exchange Interface; Gateway Interface Specification design; Data Communication Security; immunization history evaluation algorithms; patient de-duplication algorithms; programming confidentiality; vaccine code structure; Health Level 7 (HL7) data exchange standards; Information Network for Public Health Officials (INPHO); and Clinic Assessment Software Application (CASA).

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Donna Williams, Program Analyst, NIP, CDC, 1600 Clifton Road, NE, (E-62), Atlanta, Georgia 30333, telephone 404/639-8243.

Dated: May 31, 1995.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

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Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in

open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Psychopharmacologic Drugs Advisory Committee

Date, time, and place. July 24 and 25, 1995, 8:30 a.m., Gaithersburg Hilton, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Type of meeting and contact person. Open committee discussion, July 24, 1995, 8:30 a.m. to 5 p.m.; open committee discussion, July 25, 1995, 8:30 a.m. to 5 p.m.; open public hearing, 5 p.m. to 6 p.m., unless public participation does not last that long; Michael A. Bernstein, Center for Drug Evaluation and Research (HFD-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5521, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Psychopharmacologic Drugs Advisory Committee, code 12544.

General function of committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 17, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and

an indication of the approximate time required to make their comments.

Open committee discussion. On July 24 and 25, 1995, the committee will discuss issues in the design and conduct of studies involving antipsychotic drugs.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.