OTC

on the mask's current packaging, if such packaging continues to be used, which deletes the false performance claims appearing on the current packaging and which provides the affirmative disclosure about carbon monoxide required in Part II of the order.

Part IV of the order requires respondents to distribute copies of the order to their employees and agents.

Part V of the order requires respondents to maintain records for three years involving their substantiation for advertising claims.

Part VI of Emergency Devices, Inc.'s order requires them to notify the Commission thirty (30) days prior to any change in the corporate respondent.

Part VII of Emergency Devices, Inc.'s order (and Part VI of Monte Proulx's order) requires the individual respondents to notify the Commission for five years as to any new affiliation with a business which markets emergency escape masks.

Part VIII of Emergency Devices, Inc.'s order (and Part VII of Monte Proulx's order) requires the respondents to file a compliance report with the Commission within sixty (60) days after the order becomes final.

The purpose of this analysis is to facilitate public comment on the proposed orders. It is not intended to constitute an official interpretation of the complaints, agreements and proposed orders to modify in any way their terms.

Michael A. Baggage,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 355

[Docket No. 80N-0042]

Discussion of Appropriate Laboratory Testing Profiles (Testing Standards) for OTC Abrasive-Containing Fluoride Anticaries Drug Products; Public Meeting and Reopening of the Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Public meeting and reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a public meeting will be held to discuss recommendations of the Advisory Review Panel on over-the-counter (OTC) Dentifrice and Dental Care Drug Products regarding final formulation testing, i.e., "Laboratory Testing Profiles," of Category I (generally recognized as safe and effective and not misbranded) fluoride anticaries active ingredients formulated in a dentifrice (abrasive-containing) dosage form. The meeting will be structured to seek answers to the specific questions listed below in this notice.

DATES: September 26, 27, and 28, 1983, beginning at 9 a.m.

ADDRESS: Conference Rm. M, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Saul Bader, National Center for Drugs and Biologics (HFN-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4871.

SUPPLEMENTARY INFORMATION: The Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products recommended in its report published in the **Federal Register** of March 28, 1980 (45 FR 20666), that laboratory testing profiles (testing standards) for Category I (generally recognized as safe and effective and not misbranded) abrasive-containing fluoride anticaries drug products be included in the monograph for OTC anticaries drug products to insure the effectiveness of these drug products. In the preamble to the Panel's report, the agency stated that these laboratory testing profiles would not be included in the proposed monograph (advance notice of proposed rulemaking) because "the Panel's final formulation recommendations represent a new concept with many technical issues yet to be resolved" (45 FR 20666). The agency has received seven comments in response to the Panel's report urging the agency to include the laboratory testing profiles in the anticaries monograph (Ref. 1). The agency did not receive any comments that were opposed to the inclusion of the laboratory testing profiles in the anticaries monograph.

In an effort to resolve technical issues concerning the laboratory testing profiles, the Division of OTC Drug Evaluation invited comments from the Council on Dental Therapeutics of the American Dental Association, the Cosmetic Toiletry & Fragrance Association, and The Proprietary Association (Ref. 2). These organizations responded with comments ranging from recommendations to use only the nonbiological portion of the laboratory testing profiles as a standard for new fluoride dentifrice products that are formulated with an abrasive and fluoride ingredient included in the laboratory testing profiles in the Panel's report (45 FR 20679 to 20681), to requiring further laboratory testing in addition to the Panel's biological and nonbiological testing recommendations for such new formulations (Ref. 3). The administrative record for the OTC anticaries drug products rulemaking is being reopened to include this correspondence.

Under 21 CFR 10.65 the Commissioner has concluded that it would be in the public interest to hold an open public meeting to discuss the issues concerning testing profiles for OTC anticaries drug products. Therefore, the agency is inviting interested individuals or groups to discuss these issues at an open meeting to be held on September 26, 27, and 28, 1983. The questions to be considered during the meeting are:

1. Do the Panel's recommended laboratory testing profiles address all the parameters that are significant in determining the effectiveness of the product? Has the technology changed in the 5 years since the Panel recommended these testing profiles?

2. Are all of the parameters that the Panel recommended be included in the laboratory testing profiles necessary in determining the effectiveness of the product? Are the Panel's established limits for specific gravity necessary? If yes, does a lower specific gravity affect the effectiveness of the anticaries activity? If not, could the Panel's limits (specific gravity: 1.3 to 1.7) be widened to 1.1 to 1.7?

3. Are all of the test values recommended by the Panel in the laboratory testing profiles valid for the abrasive/fluoride formulations listed by the Panel?

4. Are there any laboratory testing profiles, i.e., specific standards, that could validly be applied to new abrasive/fluoride formulations not specifically listed in the Panel's profile tables? Is silica a compatible abrasive for a sodium fluoride dentifrice?

5. The Panel recommended that biological testing in addition to analytical testing be required for abrasive-containing dentifrices. The recommended biological testing would require comparison of test dentifrice formulations to certain dentifrice reference formulations. These reference formulations are discussed in a submission made to the Panel by The Proprietary Association (Ref. 4). The reference formulations are commercial products that have been clinically tested and found to be effective. They are available only from the manufacturers of these commercial products. The following questions and concerns