

Statement of Exemption and Environmental Assessment Report
for the Establishment of a
Proposed Monograph for OTC Skin Bleaching Drug Products

DATE: May 8, 1978

ADDRESS: Division of OTC Drug Evaluation (HFD-510)
Food and Drug Administration
Department of Health, Education, and Welfare,
5600 Fishers Lane, Rockville, MD 20857.

STATEMENT: The Bureau has determined that this action is exempt from the requirement of preparing an Environmental Impact Analysis Report (EIAR). The exemption of this proposed action is specified in subparagraph (4) of paragraph (f) (21 CFR 25.1(f)). This statement conforms to the requirement established in paragraph (g) (21 CFR 25.1(g)).

REPORT: The Bureau has assessed the statement of exemption for this action and has concluded that it has been correctly applied in accordance with environmental regulations. This monograph specifies the conditions under which products already in commercial distribution may continue to be marketed. The Commissioner does not anticipate that the promulgation of this monograph will significantly affect the quality of the human environment.



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Director
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Economic Impact Assessment Statement for OTC Skin Bleaching Drug Products

The Need for Inflation Impact Review

Pursuant to Executive Order 11821 (amended by Executive Order 11949) and the ensuing OMB Circular A-107 and interim HEW guidelines, FDA's proposal to establish a monograph for OTC skin bleaching drug products was evaluated for its potential inflationary impact. The criteria and the thresholds for determining if an action possesses a major inflationary impact are:

- (1) Cost (or price) increase to industry, government and consumers where the total impact exceeds 100 million dollars per year; or, where the total impact on any one industry (i.e., S.I.C. classification at the fourth digit) exceeds 80 million dollars per year.
- (2) Substantial changes in the competitive structure of an industry with value of shipments exceeding 100 million dollars annually.
- (3) Decreases in productivity requiring a net addition of 10,000 employees in public and private sectors to sustain current levels of production.
- (4) Shortages of supply of important services and/or materials where the annual dollar value of the change exceeds 100 million dollars.
- (5) Increases usage or decreases availability of energy (i.e., electricity, fuel oil, gasoline, coal, or natural gas) by 1/10 of 1 percent of more of annual domestic usage of any one of these types of fuel within a two year period.

Overview of the Proposed Regulation

In accordance with section 330.10(a)(7) the Commissioner is issuing (1) a proposed order containing the monograph establishing conditions under which OTC skin bleaching drug products are generally recognized as safe and effective and not misbranded, and (2) a statement of the conditions excluded from the monograph under which OTC Skin Bleaching drug products are not generally recognized as safe and effective or are misbranded.

Conclusion

The proposed order to establish a monograph for OTC Skin Bleaching drug products has been reviewed in accordance with the requirement of Executive Order 11821 (amended by Executive Order 11949), OMB Circular A-107, and guidelines issued by HEW. It has been found that its implementation will not cause a major inflationary impact. The following section explains the rationale underlying this determination.

Inflation Impact Review

(1) Costs

The proposed regulation will increase industry costs by a small amount. Relabeling will be required for most products now marketed. Manufacturers will not be asked to destroy labeling stocks, however, and a period of 1 year is allowed to implement the changes required and comply with the published OTC final monograph. This will permit the use of existing stocks of labels and/or package inserts.

The entire annual retail sales for all products in this field has been estimated to be approximately \$30,000,000 per year.

(2) Competition

Competition among producers of skin bleaching products will not be adversely affected by these regulations. In fact, the proposed monograph may stimulate competition among these manufacturers and new manufacturers may be induced to enter the marketplace.

(3) Productivity

The changes in formula and labeling produced by these regulations can be handled by the same personnel and the same technical capabilities now existing in each of the industries, no new equipment or personnel is required to implement them.

(4) Supply shortages

Shortages of supply of important services and/or materials will not occur.

(5) Energy consumption

No significant change in energy consumption could be expected from these regulations.