

**TAB C**



United States  
CONSUMER PRODUCT SAFETY COMMISSION  
Washington, D.C. 20207

**MEMORANDUM**

**DATE: 0 5 JAN 1998**

**TO :** Val H. Schaeffer, Ph.D. Project Manager, Minoxidil

**Through:** Warren J. Prunella, AED, EC *WJP*

**FROM :** *FHD* Fay H. Dworkin, Ph.D., Sr. Staff Coordinator, EC  
Marcia P. Robins, "'&

**SUBJECT :** Economic Considerations of a Proposal to Require Child-Resistant Packaging for Drug Preparations Containing Minoxidil

The Directorate for Economic Analysis reviewed the economic, small business, and environmental effects of the subject proposal. Attached are the findings of these reviews.

Attachment(s)

**Economic Considerations: Proposal to Require  
Child-Resistant Packaging for Drug Products  
Containing Minoxidil**

The Consumer Product Safety Commission (CPSC) enforces the Poison Prevention Packaging Act (PPPA) of 1970, which authorized standards for special or child-resistant (CR) packaging to protect children under age five from serious personal injury or serious illness due to the ingestion of hazardous household substances. As a result of a review of minoxidil toxicity, the Commission staff recommends that special packaging for products containing more than 14 mg of minoxidil in a single package be required. The requirement also would apply to all applicator closures supplied with the products. Minoxidil, in topical solution, was originally available only by prescription (Rx) for treatment of hereditary hair loss in men and women.'

The first application for a 2% over-the-counter (OTC) minoxidil product was approved in 1996 by the Food and Drug Administration (FDA). Several firms are now marketing 2% minoxidil products under generic and private labels. A 5% OTC minoxidil product for men received FDA marketing approval in November 1997 and is now on the market.

**HAIR REGROWTH TREATMENTS: PACKAGING**

OTC minoxidil-containing hair regrowth treatments are marketed in bottles that contain 60 ml (2 oz) of either 2% or 5% minoxidil solution. This amounts to 1200 mg or more minoxidil per bottle. Each bottle lasts about one month if the solution is applied twice a day according to instructions. Bottles can be purchased in single and 'twin packs', and promotional packages containing three and four bottles are also available. Some suppliers market a single product specifically labeled either for women or for men, although the product formulas are the same. Other suppliers market two products, one for men and one for women.

Staff obtained packages of eleven different minoxidil products. Each unit came with a bottle of solution and one or more applicators such as a dropper, a metered finger mechanical sprayer (finger sprayer), or an extended sprayer. Spray applicators are suggested for use where there are broad areas of hair loss. The extended sprayer, supplied with some products targeted to women, allows the user to direct the spray through the hair, onto the scalp. All eleven products contained CR bottle closures, but the accompanying applicators varied. They included

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<sup>1</sup>Minoxidil in oral tablet dosage form is used as an anti-hypertensive and is only available by prescription. It is therefore required to be in CR packaging.

CR or nonCR dropper closures, nonCR finger sprayers, and an extended sprayer attachment. Instructions accompanying some products with a finger spray applicator or an extended sprayer warned:

*The spray applicator is NOT child-resistant. If you have small children, keep the original child-resistant cap and place it back on the bottle after each use.*

#### PRODUCT SALES AND MARKETS

Staff identified 16 marketers of minoxidil-containing products from Drug Topics Redbook (a pharmacy reference book), trade press articles, and from the labels on products shelved in local area stores. Of the 16 marketers, 10 are manufacturers that have obtained FDA marketing approval. Two of the 10 manufacturers are small pharmaceutical companies. The remaining six marketers may be repackagers or relabelers. According to a pharmaceutical industry spokesperson, retail sales of brand name and generic minoxidil products amounted to about \$200 million for the 12 months ending June 30, 1997. Unit sales are estimated at 8 million. Therefore, the average unit price is about \$25.

Minoxidil hair regrowth products are sold by a variety of retail outlets including supermarkets, drug stores, and mass merchandisers. At least two products can be ordered through the Internet. Retail prices for a single 2 oz bottle have been observed in Washington, DC area stores ranging from as low as \$6 for a generic to \$30 for a brand name product. EC observed that local stores frequently sell these products at promotional or special prices and in 'Buy One Get One Free' packages.

#### EFFECTS OF THE PROPOSAL,

The proposed requirement for CR packaging for certain products containing minoxidil and for applicators supplied with these products should have no effect on relabelers of minoxidil products. Moreover, the requirement will have no economic impact on firms that are voluntarily using CR packaging on the bottle (primary package) and on its dropper applicator. Firms that are not using CR packaging and firms that enter this market in the future will be readily able to find primary packaging at prices competitive with nonCR packaging.

The proposed requirement, however, will affect firms that supply nonCR applicators with minoxidil products. Substitution of the available CR dropper will result in an estimated 5 cent per package incremental cost to the supplier. This cost increase is small relative to the \$25 average retail price of a minoxidil product.

There is no known senior friendly CR finger sprayer currently on the market. According to the Directorate for Epidemiology and Health Sciences (EH) staff, a major finger sprayer manufacturer said that his company can make available commercial quantities of a senior friendly CR finger sprayer given adequate time. We have no information at this time regarding the incremental cost of a senior friendly CR finger sprayer; a non CR sprayer is available at an estimated cost of 13-15 cents. The cost of a senior friendly CR finger sprayer is not likely to be large compared with the retail price of minoxidil.

#### EFFECTS OF THE PROPOSED RULE ON SMALL ENTITIES

One of the two known small manufacturers of minoxidil uses CR packaging for the primary packaging of its product marketed for men, but the enclosed applicator is a nonCR dropper. As mentioned above, substitution of a CR dropper could be accomplished at an incremental cost of about 5 cents per unit, which is a small fraction of the average retail price of the preparation. This manufacturer has applied for FDA approval to market a product targeted to women. The product was to have contained a nonCR finger sprayer.

Staff has no information regarding the packaging and applicators supplied with the products of the other known small minoxidil manufacturer. The company did not respond to staff's request for information.

As with larger companies that are supplying a nonCR spray applicator with minoxidil-containing products, these two (and any other unidentified) manufacturers have two options. They may either substitute a CR dropper for the nonCR dropper or nonCR finger sprayer or use a CR senior-friendly finger sprayer when it becomes available. Although the comparative costs of these options are not known at this time, the additional cost is not expected to be large relative to the price of the product.

The above information indicates that there are very few small businesses that would be affected by the CR packaging requirement and that in any event the effects are likely to be small. Therefore, at this time staff preliminarily concludes that the proposal to require special packaging for minoxidil products will not have a significant impact on a substantial number of small businesses or other small entities.

**Preliminary Environmental Assessment of Proposal to Require  
Child-Resistant Packaging for Drug Products Containing Minoxidil**

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has preliminarily assessed the possible environmental effects associated with the proposed Poison Prevention Packaging Act (PPPA) packaging requirements for drug products containing minoxidil.

The Commission's regulations at 16 CFR Sec. 1021.5 (c) (3) state that the rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. Preliminary analysis of the impact of this proposed rule indicates that child-resistant (CR) packaging requirements for the production of marketers of minoxidil-containing products under the proposed rule will have no significant effects on the environment. The manufacture, use, and disposal of CR closures will present the same environmental effects as do non-CR closures.