

TAB B

UNITED STATES GOVERNMENT

MEMORANDUM

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

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SUBJECT: Technical Feasibility, Practicability, and
Appropriateness Determination for the Proposed Rule to
Require Special Packaging for Products Containing
minoxidil.

The attached evaluation summarizes the Health Sciences determinations of technical feasibility, practicability, and appropriateness for the proposed rule for minoxidil-containing household products.

PPPA
PROPOSED RULE
MINOXIDIL
TECHNICAL FEASIBILITY,
PRACTICABILITY,
AND
APPROPRIATENESS
Charles J. Wilbur

DECEMBER 1997



DIRECTORATE FOR EPIDEMIOLOGY & HEALTH SCIENCES
DIVISION OF HEALTH SCIENCES

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SUMMARY

Epidemiology and Health Sciences staff concludes that the data support a finding that special packaging requirements for products containing minoxidil are technically feasible (can be produced), practicable (lends itself to techniques of mass production), and appropriate (compatible with the substances contained within the package), for the following:

1) Products requiring continuous threaded and dropper dispensing child-resistant packaging (CRP) with an effective date of six-months. Adequate supplies of senior friendly (SF) continuous threaded and dropper dispenser CRP are available.

2) Products using a metered finger mechanical sprayer (one with an optional extender applicator) require an effective date of one year. The child-resistant (CR) metered finger mechanical sprayer manufacturer can develop new or modify existing CRP to be SF. The time is needed to update the design and conduct protocol tests. If additional time is required to produce commercial quantities, manufacturers can apply for a stay of enforcement.

INTRODUCTION

To require that all minoxidil-containing products be packaged in CRP the Commission must find that CRP is:

o Technically Feasible - Technology exists to produce packaging conforming to the standards.

o Practicable - Special packaging complying with the standards, can be produced using modern mass production and assembly line techniques.

o Appropriate - Packaging complying with the standards, adequately protects the integrity of the substance and does not interfere with its intended storage or use.

The PPPA stipulates that the effective date shall be no sooner than 180 days and no more than one year from the date the final standard was promulgated.

TECHNICAL FEASIBILITY

Minoxidil-containing oral prescription drugs are presently regulated under the PPPA. All known over-the-counter (OTC) minoxidil-containing products are currently in SF CR continuous threaded packaging. In addition, packages contain one or more application devices (i. e. dropper, metered mechanical pump spray, and/or metered mechanical pump spray with an extender applicator). Some, but not all of the applicators are SF CRP. Table I, Minoxidil Packaging, describes thirteen representative marketed products that were purchased at retail or obtained from the product manufacturer. As indicated in the table, there are SF CR droppers available on the market that are currently packaged with some OTC minoxidil preparations. No SF CR metered finger mechanical sprayer is currently being used. There is one CR finger mechanical sprayer that can be made SF.

Various types and designs of SF CR packaging can be obtained. See ASTM D3475, Standard Classification of Child-Resistant Packages. Each type of packaging is addressed below:

PRODUCT CONTAINER

CONTINUOUS THREADED RECLOSABLE CR PACKAGING: Thirteen representative products are voluntarily using a SF ASTM IA (Push Down and Turn Type) packaging". In addition various designs of SF continuous threaded (screw) type reclosable CR packaging are readily available. ASTM in its Standard Classification of Child-Resistant Packages lists several designs of type I packages that are SF. Most minoxidil products use this type of CRP.

PRODUCT APPLICATORS

CONTINUOUS THREADED RECLOSABLE CR DROPPER PACKAGING: Eight known products presently have ASTM IA design dropper packaging^{5-10,13,14} that are reported to be SF¹⁵⁻¹⁷. The three products that are using non-CR droppers^{3,4,12} can convert to SF CR droppers¹⁶⁻¹⁸. Alternatively, they could package a dropper that cannot be used as a closure. This would encourage people to close the package with the original SF CRP.

METERED FINGER MECHANICAL SPRAYER CR PACKAGING: We know of eight minoxidil products using a non-CR metered finger mechanical sprayer dispensing mechanism". Some products contain instructions that include the statement, e. g. "The spray (B) applicator is NOT child-resistant." A similar CR metered finger mechanical sprayer attached to a CR cap can be made available. It would need to be protocol tested to find out its senior adult use effectiveness (SAUE)²⁰. The finger pump manufacturer has indicated they can make available (given adequate time) a SF CRP²¹. It would consist of a locking mechanism that provides the child resistance for the SF metered finger mechanical sprayer mounted on a reclosable SF CR closure that can be attached to a plastic bottle. Approximately twelve months is needed to make modifications to the CRP design, modify production molds, and conduct protocol tests.

TABLE I: Minoxidil Packaging.

MINOXIDIL CONTAINING PRODUCTS, 2%					
PACKAGE					
Company	For	Product Container	Applicators		
			Dropper	Finger Sprayer	Extender Applicator •
3	Women	SF	-	NCR	NCR
1	Women	SF		NCR	NCR
1	Women	SF	SF	NCR	NCR
2	Women	SF	SF	NCR	
1	Men**	SF	SF	NCR	
1	Men	SF	SF	NCR	
2	Men	SF	SF	NCR	
4	Men	SF	SF	NCR	
5	Men	SF	SF		
6	Men	SF	SF		
7	Men	SF	NCR		
8	Men	SF	NCR		
3	Men	SF	NCR		

SF=Senior Friendly

NCR=Non-Child Resistant

• Extender Applicator Uses Metered Finger Mechanical Sprayer Mechanism.

• • Minoxidil, 5%.

g:/minoxidl.wb1

If additional time is required to produce commercial quantities, manufacturers could apply for a stay of enforcement for this package type.

Three known products for women have a non-CR extender applicator that must be attached to the mechanical pump dispensing mechanism^{2,11,13}. This extender applicator is used to ".help you spray through the hair, directly onto the scalp." This optional extender spray applicator attached to a CR and SF metered finger mechanical sprayer mechanism could provide the required special packaging for the extender applicator. Another possibility is to use another type of CR mechanism to accomplish the same purpose, i.e., a SF CR dropper²². One product for women currently on the market uses the SF CR dropper for this purpose.

The staff believes that data support the finding that special packaging of minoxidil-containing products using SF continuous threaded (screw) CRP, SF dropper CRP, and SF metered mechanical finger pump CRP, with extended spray applicator, are technically feasible.

PRACTICABILITY

Information is available to support the finding that the special packaging of minoxidil-containing products is practicable.

PRODUCT CONTAINER

CONTINUOUS THREADED (CT): These types of SF CRP are presently being used by many companies for regulated products, i.e., thirteen minoxidil products use SF CT special packaging. Companies have implemented assembly line and mass production techniques in their manufacturing process for the CT CRP. This shows that it is practicable to package regulated products in this type of special packaging. No major problems are anticipated from the manufacturing standpoint.

PRODUCT APPLICATORS

CONTINUOUS THREADED RECLOSABLE CR DROPPER PACKAGING: Eight minoxidil products voluntarily use SF dropper applicators. These companies have carried out assembly line and mass production techniques in their manufacturing process. This shows that it is practicable to package regulated products in this type of special packaging. No major problems are anticipated in this change from the manufacturing standpoint. Companies not currently using SF CR dropper applicators can incorporate special packaging into their existing packaging lines.

METERED FINGER MECHANICAL SPRAYER CR PACKAGING: No known minoxidil product manufacturer is currently using a CR metered finger mechanical sprayer. However, it is anticipated that a SF CR metered finger mechanical sprayer and a SF CR optional extender spray applicator would be similar to the one being used. Thus, no changes would be necessary to the assembly line and mass production technique in the manufacturing process. Existing packaging lines could be used.

APPROPRIATENESS

CONTINUOUS THREADED CRP AND DROPPER SPECIAL PACKAGING: Some companies are presently using these types of SF special packaging for their products, i.e., thirteen minoxidil products use an SF CR CT package and eight a CT dropper type special package. Most companies can use existing CR packaging designs and materials that have proven not to be detrimental to the integrity of the substance and have not interfered with its storage or use for these types of CRP. Product shelf-life, and integrity would not be expected to change, as it is anticipated that the same packaging materials could be used in contact with the product.

METERED FINGER MECHANICAL SPRAYER CR PACKAGING: No known minoxidil product manufacturer is presently using a CR metered finger mechanical sprayer. Assuming the non-CR and the SF CR metered finger mechanical sprayers and the optional extender spray applicators use similar materials, we would not expect the materials to be detrimental to the integrity of the substance nor would they interfere with its storage or use. Therefore, product shelf-life, and integrity would not be expected to change, as it is anticipated that the same packaging materials could be used in contact with the product.

Staff, therefore, believe that the data support the finding that special packaging for minoxidil-containing products is appropriate.

EFFECTIVE DATE

CONTINUOUS THREADED CRP AND DROPPER CR PACKAGING: A six-month effective date is reasonable for these types of special packaging. All manufacturers are voluntarily using CT SF CRP for the primary container. Additionally, a product applicator is needed, e.g., SF CR dropper. Most, but not all, manufacturers are voluntarily using SF dropper CRP. Two sizes of SF dropper CRP are commercially available. Most product manufacturing companies would not require any changes to their production lines. The CRP suppliers have the requisite molds, assembly equipment, lining material and plastic resins to supply the required CRP quantities for this product. Adequate supplies of SF CRP for this product are available from the packaging manufacturer.

METERED FINGER MECHANICAL SPRAYER AND EXTENDER SPRAY APPLICATOR CR PACKAGING: An effective date of one year is needed for products using the metered finger mechanical sprayer type packaging. If additional time is necessary, companies that show a good faith effort can request a stay of enforcement²³. One year is needed to achieve a SF design, to obtain molds and conduct child and senior friendly protocol tests. If additional time is needed to initiate production and make available commercial quantities the packaging manufacturer may request a stay of enforcement. If the metered SF metered finger mechanism sprayer special package was in combination with the extender spray applicator, the timing would be approximately the same.

CONCLUSION

Staff concludes that data support the findings that ASTM types I (CT), I (Dropper), and IX (Pump Dispenser) special packaging for minoxidil products is technically feasible, practicable, and appropriate.

RECLOSABLE CONTINUOUS THREADED CRP AND DROPPER CRP,(ASTM I):

There are regulated PPPA products on the market with ASTM type I CRP (with and without a dropper) that comply with SAUE requirements. Adequate supplies of SF CRP are available to support a six-month effective date.

METERED FINGER MECHANICAL SPRAYER CRP, (ASTM IX) AND EXTENDER SPRAY APPLICATOR CRP:

The CR metered finger mechanical sprayer manufacturer said, with adequate time, they can make commercially available SF special packaging. One year is needed for the metered CR finger mechanical sprayer company to redesign, obtain molds, protocol test, and start commercial production. If additional time is necessary to ensure adequate supplies of new SF and CR packaging a stay of enforcement can be requested. The same is true if the metered finger mechanical sprayer is used with the extender sprayer applicator.

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