

does not require FDA to prepare a statement of costs and benefits for this final rule, because the rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation. The current inflation adjusted statutory threshold is about \$110 million.

The purpose of this final rule is to establish a monograph for ingrown toenail relief drug products for OTC human use and include sodium sulfide 1 percent in a gel vehicle in the monograph. This final rule provides for OTC availability of this type of product.

Manufacturers who wish to market this type of product have the standard costs associated with the introduction of any new product. These include preparation of labeling, stability testing, and implementing manufacturing procedures. Any cost incurred will be voluntary if manufacturers elect to market this type of product. This cost may vary from manufacturer to manufacturer; however, the burden on small manufacturers is not greater than that for large manufacturers. Manufacturers will not incur any costs related to proving safety and effectiveness of the active ingredient for this intended use.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule allows manufacturers to market OTC ingrown toenail relief drug products containing sodium sulfide 1 percent in a gel vehicle without having to obtain an approved new drug application, as is currently required, and is beneficial to small entities. Thus, this final rule will not impose a significant economic burden on affected entities. Therefore, under the Regulatory Flexibility Act, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 358

Labeling, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 310 and 358 are amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

■ 2. Section 310.538 is amended by removing the ingredient sodium sulfide in paragraph (a) and by adding paragraph (e) to read as follows:

§ 310.538 Drug products containing active ingredients offered over-the-counter (OTC) for use for ingrown toenail relief.

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(e) This section does not apply to sodium sulfide labeled, represented, or promoted for OTC topical use for ingrown toenail relief in accordance with part 358, subpart D of this chapter, after June 6, 2003.

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 358 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 4. Part 358 is amended by adding new subpart D, consisting of §§ 358.301 to 358.350, to read as follows:

Subpart D—Ingrown Toenail Relief Drug Products

Sec.

358.301 Scope.

358.303 Definitions.

358.310 Ingrown toenail relief active ingredient.

358.350 Labeling of ingrown toenail relief drug products.

Subpart D—Ingrown Toenail Relief Drug Products

§ 358.301 Scope.

(a) An over-the-counter ingrown toenail relief drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter 1 of title 21 unless otherwise noted.

§ 358.303 Definitions.

As used in this subpart:

(a) *Ingrown toenail relief drug product.* A drug product applied to an ingrown toenail that relieves pain or discomfort either by softening the nail or by hardening the nail bed.

(b) *Retainer ring.* A die cut polyethylene foam pad coated on one side with medical grade acrylic pressure-sensitive adhesive. The retainer ring has slots, center-cut completely through the foam with the cut of sufficient size to allow for localization of an active ingredient in a gel vehicle to a specific target area. The retainer ring is used with adhesive bandage strips to place over the retainer ring to hold it in place.

§ 358.310 Ingrown toenail relief active ingredient.

The active ingredient of the product is sodium sulfide 1 percent in a gel vehicle. The gel vehicle is an aqueous, semisolid system with large organic molecules interpenetrated with a liquid.

§ 358.350 Labeling of ingrown toenail relief drug products.

(a) *Statement of identity.* The labeling of the product contains the established