the petitioner does not have any airplanes in operation.

Second, it is also FAA policy that no prospective relief be granted. Section 91.851 defines "new entrant" as an air carrier that begins operating after November 5, 1990. Since the petitioner has not yet achieved FAA certification to operate, it is not yet operating under the provisions of § 91.867 to be considered a new entrant or to ask relief from that regulation.

Further, even if the petition were not inappropriate for these reasons, it would still fail on it merits. The primary basis of the petitioner's argument is its "strategic business plan" that calls for the operation of one type of aircraft. The petitioner has noted that such airplanes are not available domestically, but has chosen to remain with that plan and seek exemption from a legislative prohibition. The petition does not contain the required financial information or any other data concerning acquisition costs to support its statement that compliance would be financially onerous. Since the petitioner claims to be a new entrant, it does not have a compliance plan on file, but neither does the petition include the petitioner's plan for compliance nor any evidence of how the petitioner would meet future interim compliance requirements were the requested relief ranted.

The FAA has determined that, taken together, these arguments demonstrate neither reasonableness nor good faith in applying for a waiver. Instead of changing its business plan to meet the requirements of a regulation that has been in place since 1991, the petitioner has requested that it be grandfathered into the compliance schedule as if it had begun operation already, and then asks that that relief be extended beyond what would be required if it had commenced operations. Simply put, if the petitioner cannot affort to commence operation according to the regulations, the FAA can have little expectation that the petitioner will ever be able to comply, and the only good faith action is for the petitioner to adjust its business plans accordingly, a course of action that the petitioner has already expressed it is unwilling to take.

Moreover, the petitioner fails to state any reasonable public interest that would be served by granting the requested relief, if it were available. The FAA considers full compliance with the interim compliance requirements to be in the public interest, and any waiver ranted from an interim requirement ast reflect a net public benefit when ghed against noncompliance with the rule. The petitioner has stated but not shown that there is an "unfulfilled need" for the contemplated service between Philadelphia, Pittsburgh, and Detroit, but the data it submitted regarding the current available service rebuts this. While the petitioner states that its contemplated service will be at much lower fares than currently available, the only evidence is the petitioner's plan to charge less and its general statements that dramatic fare reductions have been achievable by other carriers in other markets.

Taken as a whole, these general statements are not convincing that the waivers required to achieve this contemplated service in any manner outweighs the public interest in a quieter environment as established by Congress and in compliance with the regulations in general. The petitioner has not presented any logical evidence how the failure to grant relief could have a negative impact on competition or fares, since the petitioner is not yet offering any competing service nor has it presented evidence that it will be able to operate for lower fares; as yet, there are no aircraft on which to even base cost estimates. The petitioner's claim of adverse effect on service to small communities surrounding the market cities is oxymoronic, since considerations of service to small communities have historically had no relation to service from the closest large cities. Finally, to allow the petitioner to begin operation without being subject to the same rules under which its competition operates would be markedly unfair to the operating carriers in those markets who have met the requirements with the same notice and market conditions affecting the petitioner.

Accordingly, the FAA has determined that the petitioner's requested relief from § 91.855 is outside the authority of the FAA to grant, that its petition requesting relief under § 91.867 is inappropriate given its lack of certification and current operation, and that the arguments presented in its petition do not reflect a good faith attempt to comply with the regulations and are not in the public interest.

In consideration of the foregoing, I find that the request for a waiver is not in the public interest. Therefore, by the authority delegated to me by the Administrator, the petition for a waiver by AirTran Corporation to § 91.865, pursuant to § 91.871, is hereby denied.

Issued in Washington, DC on November 17, 1994.

Louise E. Maillett,

Director of Environment and Energy.

[FR Doc. 94–28916 Filed 11–18–94; 3:36 pm]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 80N–0238]

RIN 0905–AA06

Wart Remover Drug Products for Over-the-Counter Human Use; Amendment of the Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the final monograph for over-the-counter (OTC) wart remover drug products to revise the directions for products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: November 23, 1995.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 1990 (55 FR 33246), FDA issued a final monograph for OTC wart remover drug products (21 CFR part 358). The final monograph included in § 358.110(c) (21 CFR 358.110(c)) products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. Such products were included in the monograph based on the agency's evaluation of data from three clinical studies (Ref. 1). (See comment 13, 55 FR 33246 at 33253.) The directions for such products were included in § 358.150(d)(3) (21 CFR 358.150(d)(3)) as follows:

"Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly." (If appropriate: "Cut plaster to fit wart.") "Apply medicated plaster at bedtime, leave in place for at least 8 hours; in the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

In discussing the labeling for these products (also in comment 13), the agency stated:

If there are any special directions that relate to using a particular product, then such information should appear as part of the manufacturer's additional directions for the product. The monograph provides the minimum directions necessary for use of the product. Manufacturers may supplement these directions with additional information necessary to use their specific product. For example, the agency notes that the manufacturer's directions for its specific product include statements to "keep plastic film on the top of pad facing up and to apply sticky bottom side to the wart." The agency finds no need to include such directions in this final monograph; however, manufacturers may add such information, as appropriate, to the labeling of their products.

Subsequently, the agency became aware that a manufacturer of this product had the following additional statements in its product's labeling (Ref. 2): (1) "Smooth wart surface with emery file supplied," and (2) "Apply a drop of warm water to the wart, keeping the surrounding skin dry." The agency has rereviewed the clinical studies (Ref. 1) for this product and determined that this additional labeling information is based on the manner in which the clinical studies were performed. The agency notes that use of an emery file and application of a drop of warm water to the wart site as part of the directions for this type of product were not included in the labeling suggestions made by the manufacturer when the final monograph was being prepared (see comment 13, 55 FR 33246 at 33253).

The agency is concerned that similar products in the marketplace may have different directions—some recommending use of an emery file and a drop of warm water to prepare the wart site and others not mentioning use of an emery file and a drop of warm water. Because of concerns that this situation could lead to consumer confusion, in the **Federal Register** of January 28, 1994 (59 FR 4015), the agency proposed to amend the final monograph for OTC wart remover drug products to revise the directions for products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. The agency proposed that the directions in § 358.150(d)(3) be revised to read as follows:

"Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly. Gently smooth wart surface with emery file supplied." (If appropriate: "Cut plaster to fit wart.") "Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

References

(1) Comment No. RPT2, Docket No. 80N–0238, Dockets Management Branch.

(2) Labeling for Trans-Ver-Sal, included in OTC Vol. 16CFMA, Docket No. 80N–0238, Dockets Management Branch.

Interested persons were invited to submit written comments by March 29, 1994. One manufacturer of OTC wart remover drug products submitted a comment in response to the agency's proposal. Copies of the comment are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

The manufacturer stated that it marketed a 15 percent salicylic acid in karaya gum product in a glycol plaster vehicle. The comment agreed with the agency's proposal and commended the agency's efforts in updating the product directions to be consistent with the original clinical methods used during its development. The comment stated that this revision to include use of an emery file and a drop of water is in keeping with the long marketing history of this product.

The comment pointed out that some mild abrasion is unavoidable while preparing the treatment site with the emery file and that the karaya gum vehicle minimizes the potential for irritation associated with any such abrasion. The comment added that the drop of water helps facilitate the initiation of the keratolytic action when the salicylic acid is applied.

The agency appreciates the comment's support. Accordingly, the agency is finalizing the proposed revised directions in § 358.150(d)(3) for 15 percent salicylic acid in a karaya gum, glycol plaster vehicle identified in § 358.110(c).

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (59 FR 4015 at 4016). FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this rulemaking is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule will impose direct one-time costs associated with changing product labels for OTC wart remover drug products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. There are only a few such products in the marketplace. Relabeling should be a nominal cost, and manufacturers will have 1 year after publication of this final rule to implement this labeling. Thus, this rulemaking for OTC wart remover drug products is not expected to have an impact on small businesses. Accordingly, the agency certifies that this amendment to the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency has determined under 21 CFR 25.24(c)(6) 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.

As discussed in the proposal (59 FR 4015 at 4016), the agency advised that any final rule resulting from the proposed rule would be effective 12 months after its date of publication in the **Federal Register**. Therefore, on or after November 23, 1995, any OTC wart remover drug product that is not in compliance with this final rule may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application or abbreviated application. Further, any OTC drug product subject to this final rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date that the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the final rule at the earliest possible date.

List of Subjects in 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 part 358 is amended as follows:

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

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

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 358.150 is amended by revising paragraph (d)(3) to read as follows:

§ 358.150 Labeling of wart remover drug products.

* * * * *

(d) * * *

(3) *For products containing salicylic acid identified in § 358.110(c).* "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly. Gently smooth wart surface with emery file supplied." (If appropriate: "Cut plaster to fit wart.") "Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

* * * * *

Dated: November 8, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94–28857 Filed 11–22–94; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 870

Abandoned Mine Reclamation Fund—Fee Collection and Coal Production Reporting

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of suspension.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) of the United States Department of the Interior (DOI) is suspending a portion of permanent program regulations found at 30 CFR 870.5 which defines the term *Qualified hydrologic unit.* This action is being taken in order to assure that the language of this definition comports with the language of Title IV of the Surface Mining Control and Reclamation Act (SMCRA) of 1977, as amended by the Omnibus Budget Reconciliation Act of 1990 (November 5, 1990) which included the Abandoned Mine Reclamation Act of 1990, as amended, and by the Energy Policy Act of 1992 (October 24, 1992).

EFFECTIVE DATE: November 23, 1994.

FOR FURTHER INFORMATION CONTACT: Norman J. Hess, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue, N.W., Washington, DC 20240, Telephone: 202–208–2949.

SUPPLEMENTARY INFORMATION:

I. Background

The Abandoned Mine Land (AML) Reclamation Program was established by SMCRA, Public Law 95–87, 30 U.S.C. 1201 et seq., in response to concern over extensive environmental damage caused by past coal mining activities. On October 25, 1978, OSM published final regulations implementing an AML Reclamation Program incorporating the provisions of Title IV of SMCRA. OSM published revisions to these regulations on June 30, 1982, in response to the Administration's request for regulatory review. On November 5, 1990, the President signed into Law the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, which included the Abandoned Mine Reclamation Act of 1990, as amended. In addition to extending the authority to collect reclamation fees, the amendments to Title IV contained several significant provisions. OSM published proposed rules at 56 FR 57376–57401 (November 8, 1991) implementing the 1990 amendments to Title IV of SMCRA and requested comments from the public. On October 24, 1992, the President signed into law the Energy Policy Act of 1992, Public Law 102–486. Included in this law were several additional amendments to the AML Reclamation Program under Title IV of SMCRA. These amendments were incorporated into the rulemaking and the Abandoned Mine Land Reclamation Fund Reauthorization Implementation final regulations were published at 59 FR 28136–28174 (May 31, 1994).

II. Discussion of Definition Suspended

The final rule noted above amended the definitions in Section 870.5 for "eligible lands and water," and "left or abandoned in either an unreclaimed or inadequately reclaimed condition," and added new definitions for "mineral owner" and "qualified hydrologic unit." The new definitions updated these terms so that they would be consistent with the recent amendments to SMCRA. The definitions reflect additional eligibility for lands adversely affected by mining between August 3, 1977 and November 5, 1990; for noncoal lands after certification of the reclamation of all known coal problems; for water projects; and finally for lands affected by qualifying operations.

The term *Qualified hydrologic unit* has been defined at Section 870.5 of the final regulation. Statutory language contained in SMCRA Section 402(g)(7)(D) stipulates that a qualified hydrologic unit must include lands and waters which are eligible pursuant to Section 404 and include any of the first three priorities as stated in Section 403(a), *and* (2) proposed to be the subject of expenditures by the State/Indian tribe (from amounts available from the forfeiture of bonds required under Section 509 or from other State/Indian tribe sources) to mitigate acid mine drainage. In Section 870.5 of the regulation, OSM substituted *or* for *and* thereby making both categories independently eligible for funding. Concern has been raised as to whether the language of the regulation is consistent with the language of the statute in that it inappropriately broadens the definition beyond that allowed by the statute. Due to this concern, the definition of *Qualified hydrologic unit* contained in Section 870.5 of the regulations is suspended in so far as it does not require a hydrologic unit to be both (1) eligible pursuant to Section 404 and include any of the first three priorities stated in Section 403(a), and (2) proposed to be the subject of expenditures by the State (from amounts available from the forfeiture of a bond required under Section 509 or from other State sources) to mitigate acid mine drainage in order to be considered a qualified hydrologic unit.

III. Procedural Matters

Federal Paperwork Reduction Act

This Notice of Suspension does not contain collections of information which require approval by the Office of Management and Budget under 44 U.S.C. 3501 et seq.

Executive Order 12866

This Notice of Suspension has been reviewed under Executive Order 12866.