UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE REGIONAL ADMINISTRATOR

5/3/77

In the Matter of

Ortho Industries, Inc.,	)	I. F. & R. Docket No. II-129C
	)	
Respondent	)	INITIAL DECISION

Preliminary Statement

This is a proceeding under section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 l(a) for the assessment of a civil penalty for holding for sale, in violation of section 12(a)(1)(E) of the Act, 7 U.S.C. 136j(a)(1)(E), the product PBF Shoe Spray, a pesticide, that was adulterated and misbranded. The complaint was issued on June 21, 1976 and a civil penalty of $700 was proposed to be assessed.[1/] The respondent filed an answer contesting the amount of the proposed penalty.

Pursuant to section 168.35(a) of the Rules of Practice issued for the conduct of proceedings of this type (40 CFR, Part 168) the undersigned corresponded with the parties for the purpose of accomplishing some of the objectives of a prehearing conference. A hearing in the case was held in New Rochelle, New York, on March 8, 1977. The complainant was represented by Susan Levine, Esq., of the EPA Enforcement Division, Region II, New York, and respondent was represented by Dr. Jack J. Silverman, president of respondent corporation. The complainant has submitted proposed findings of fact, conclusions of law, and a proposed order. The respondent did not submit proposed findings or conclusions but it did submit a reply to the

1/ The complaint, as originally filed, proposed a civil penalty of $280. On complainant's motion, this amount was increased to $700.

to the documents submitted by the complainant. These have been given due consideration.

Findings of Fact

1. The respondent, Ortho Industries, Inc., has a place of business in New Rochelle, New York. The company is engaged primarily in manufacturing molded shoes on special order.

2. The company had manufactured for it and also sold a product called PBF Shoe Spray to be used in spraying the interior surface of shoes. The principal purpose for which the product was sold by respondent was as a fungicide to disinfect the interior surfaces of shoes that were likely to be contaminated by athlete's foot fungi [Trichophyton mentagrophytes (interdigitale)].

3. PBF Shoe Spray is a pesticide for which respondent obtained registration from the United States Department of Agriculture (predecessor of EPA for registering pesticides) in July 1968.

4. On April 9, 1975 the respondent held for sale at its place of business in New Rochelle, New York, a number of cans each containing 5 ounces of the product PBF Shoe Spray. The label on each of the cans represented that the product contained as active ingredients.

Methyldodecybenzyl trimethyl ammonium chloride	.048%
Methyldodecylxylylene bis (trimethyl ammonium chloride)...	.012%

The product contained only .033% ammonium chlorides and was 45% deficient in such constituents.

5. The product that respondent held for sale on April 9, 1975 was adulterated within the meaning of section 2(c)(1) of FIFRA, 7 U.S.C. 136(a)(1), in that its strength fell below the professed standard of quality expressed on its label.

6. The said product was misbranded within the meaning of section 2(q)(1)(A) of FIFRA, 7 U.S.C. 136(q)(1)(A), in that its label bore a statement relative to its ingredients which was false and misleading.

7. The respondent violated section 12(a)(1)(E) of FIFRA, 7 U.S.C. 136j(a)(1)(E) in that it held for sale on April 9, 1975, a pesticide which was adulterated and misbranded.

8. The respondent is subject to the imposition of a civil penalty under section 14(a)(1) of FIFRA, 7 U.S.C. 136 l(a)(1).

9. Taking into consideration the size of respondent's business, the effect on respondent's ability to continue in business and the gravity of the violation it is determined that a civil penalty of $630 for the violations in question is appropriate.

Discussion and Conclusions

Dr. Jack J. Silverman, president of respondent company, is a doctor of podiatry. The company manufactures molded shoes on special orders that it receives from doctors and their patients and others who need corrective type of shoes. In 1967 Dr. Silverman developed a formula that he thought would be appropriate for use as a spray for the interior of shoes to prevent reinfection from fungi that cause athlete's foot. He consulted officials at the United States Department of Agriculture (USDA) (predecessor of Environmental Protection Agency for registering pestides) for the purpose of obtaining a registration. After consulting

with them he decided to use a different formula in which the active ingredient would be a product called Hyamine 2389 manufactured by Rohm and Haas, a manufacturing chemical company located in Philadelphia, Pennsylvania.

After submitting the required information to the proper authorities at USDA, the product called PBF Shoe Spray was accepted for registration on July 26, 1968.

The respondent arranged with Bellern Research Corporation of Saugerties, New York, to package the product for it in 5 ounce aerosol cans. Bellern obtained the Hyamine 2389 from Rohm and Haas. Respondent supplied the labels or the contents thereof. Bellern packaged the product, applied the labels, and shipped the packaged product to respondent. The label, among other things, represented that the product was fungicidal and that it "may be used for disinfection of environmental surfaces likely to be contaminated by athlete's foot fungi". The only direction for use was as a fine mist spray to cover the interior of shoes with instructions as to frequency of use. The active ingredients on the label showed total ammonium chlorides of .060% (see Finding 4).

Several cans of the product which respondent was holding for sale at its place of business was collected as a sample by an EPA Consumer Safety Officier on April 9, 1975. Analysis of the product showed that it contained only .033% ammonium chlorides. The product when tested by EPA microbiologists showed that it failed to kill a fungus that

causes athlete's foot (Trichophyton mentagrophytes) in 7 out of 10 tests. A microbiologist testified that to be effective as a fungicide it should have been effective in each of the 10 tests.

The product was adulterated and misbranded as set forth in Findings 5 and 6.

A civil penalty is imposable and the question is the amount of the penalty. The same evidence will establish both the adulteration and misbranding and only one penalty may be imposed. Blockburger v. United States, 284 U.S. 299, 304 (1932); Tesciona v. Hunter, 151 F.2d 589, 591 (10th Cir. 1945).

In determining the amount of penalty that should be imposed for a violation, section 14(a)(3) of FIFRA, 7 U.S.C. 136 l(a)(3) sets forth the following factors that shall be considered: size of respondent's business; effect on respondent's ability to continue in business; and gravity of the violation. Section 168.60(b)(2) of the Rules of Practice provides that there shall also be considered respondent's history of compliance with the Act and evidence of good faith or lack thereof.

The proposed civil penalty of $700 was derived from the Guidelines for Assessment of Civil Penalties under section 14(a) of FIFRA, 39 F.R. 27711, et seq., July 31, 1974. As to size of respondent's business, the testimony from Dr. Silverman was the respondent's gross sales for the previous fiscal year were in the vicinity of $225,000.

Dr. Silverman testified that the gross sales of the product in question have been up to $3,000 per year. He urges that the volume of

sales of this product and not gross sales of the company should be used in determining size of business. The statute does not state that the volume of sales of a particular violative product or of all pesticides sold by a company should be used in determining size of business. Gross sales of a business is an appropriate measure for determining size of business.

The respondent in its post-hearing submission alleged that imposition of the proposed penalty will effect its ability to continue in business. However, it presented no evidence to support the allegation.

I then reach the point of determining the appropriate penalty based on "gravity of the violation". It has generally been accepted by Administrative Law Judges that "gravity of the violation" should be considered from two aspects - gravity of harm and gravity of misconduct.

As to gravity of harm, the evidence shows that respondent has been distributing a product that was represented as effective as a fungicide in treating athlete's foot and that it would not be effective for this purpose.

The respondent urges that the product was not for general sale to consumers but that it was sold to doctors of podiatry as an adjunct treatment for athlete's foot on an experimental basis to see whether or not it was necessary to spray shoes. There was evidence that the product was sold over-the-counter directly to consumers at respondent's place of business. The label did not restrict its use to doctors of podiatry or for experimental purposes. The label represented the product as a

broad spectrum microfungicidal spray for disinfection of surfaces likely to be contaminated by athlete's foot fungi. The directions for use were designed for the consumer. The intended use of a product may be determined from its label. United States v. 681 Cases ... Kitchen Klenzer, 63 F.Supp. 286 (E.D. Mo. 1945); United States v. Article Labeled in Part ... Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969) and cases cited therein.

The respondent has suggested that deficiency of the active ingredients may have come about because Bellern, in formulating the product, used a 50% concentrate believing that it was a 100% concentrate. If this is the fact, then this product may never have been manufactured up to full strength.

The consumer of the product would use it in the belief that it would be effective in destroying the fungus that causes athlete's foot when in fact it would not be so effective. This could result in reinfection from the contaminated shoes and render ineffective other treatment being utilized in the treatment of this condition.

Turning now to gravity of misconduct. The respondent was registrant and distributor of the product. As such, it had the responsibility to see to it that the strength of the product was as represented on the label. The respondent never checked Bellern's manufacturing process nor did it ever have any tests made to determine if the product was properly formulated. The respondent cannot shift the responsibility as to the integrity of the product to the formulator. In United States v. Parfait Powder Puff Co., 163 F.2d 1008 (7th Cir. 1947) cert. denied 332 U.S. 851, the

distributor was charged with shipment of a product in violation of the Federal Food, Drug, and Cosmetic Act. The distributor disclaimed responsibility and sought to place it on the manufacturer of the product. In rejecting this argument, the court said, p.1010:

> The person who brings goods into commerce, by whatever means or implements, is bound to see that the commodity thus put in commerce, is not beyond the pale of the legislative act.

I do not find that this was a deliberate or intentional violation by respondent. However, intent or awareness of wrongdoing is not an element of the offense under the civil penalty provision of the Act. (Cf. United States v. Dotterweich, 320 U.S. 277 (1943); Parfait Powder Puff Co. v. United States, supra. Lack of intent may be considered as a mitigating factor. There was no evidence to show that respondent has a history of non-compliance with the Act. The respondent has represented that the product has been taken off the market.

The violation in question resulted from the negligence of respondent in disregard of its responsibility to see that the product it offered for sale complied with the requirements of the law.

As above noted, the proposed penalty of $700 was derived from the Guidelines. While I may consult or rely on the Guidelines, I may at my discretion increase the assessed penalty from the amount proposed. Taking into account the fact the violation was unintentional and also the fact the respondent has no history of prior non-compliance with the Act, I am of the view that the proposed penalty should be reduced by 10%. [See Rules of Practice, section 168.45(b).]

Accordingly, I propose that the following order be issued.

Final Order[2/]

Pursuant to section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended [7 U.S.C. 136 l(a)(1)], a civil penalty of $630 is assessed against respondent, Ortho Industries, Inc., for the violation which has been established on the basis of the complaint issued on June 21, 1976, as amended on September 9, 1976.

Bernard D. Levinson
Administrative Law Judge

May 3, 1977

2/ Unless appeal is taken by the filing of exceptions pursuant to section 168.51 of the Rules of Practice, or the Regional Administrator elects to review this decision on his own motion, the order shall become the final order of the Regional Administrator. [See section 168.46(c).]