

constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98-25845 Filed 9-25-98; 8:45 am]

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FEDERAL TRADE COMMISSION

[File No. 972-3159]

Pfizer Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before November 27, 1998.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Linda Badger or Kerry O'Brien, San Francisco Regional Office, Federal Trade Commission, 901 Market St., Suite 570, San Francisco, CA 94103. (415) 356-5270.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for September 18, 1998), on the World Wide Web, at "<http://www.ftc.gov/os/actions97.htm>." A paper copy can be obtained from the FTC Public Reference Room, Room H-130, Sixth Street and Pennsylvania

Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondent Pfizer Inc.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

Pfizer Inc. ("Pfizer") markets a variety of over-the-counter pharmaceuticals, including "RID Lice Killing Shampoo." RID is a shampoo (or "pediculicide") sold to treat people who suffer from head lice infestations. The RID package includes a comb for use in removing lice eggs. The Commission's complaint alleges the Pfizer's advertising for RID included false and unsubstantiated claims that: (1) RID Lice Killing Shampoo cures lice infestations in a single treatment; (2) the RID egg removal comb is one hundred percent effective; (3) clinical studies prove that RID Lice Killing Shampoo cures lice infections in a single treatment; and (4) clinical studies prove that the RID egg removal comb is one hundred percent effective.

In fact, the complaint alleges that RID is based on a pesticide which is not one hundred percent effective against lice eggs. Consumers should be aware of this limitation and make every effort to physically remove lice eggs. In addition, when this type of pediculicide is used, consumers are instructed to apply a second treatment in seven to ten days to kill any newly hatched lice. In addition, the complaint explains that the RID comb, included with the shampoo, is not necessarily one hundred percent effective. Lice eggs are difficult to see and to remove. The effectiveness of the comb is largely dependent on the skill and tenacity of the comb.

The complaint further explains why clinical studies do not prove that RID cures lice infestations in a single treatment. Specifically, the complaint alleges that the study Pfizer relied upon to make this claim included the

application of a single treatment, along with a thorough combing that removed all lice eggs. Moreover, the studies relied upon the claim that the RID egg removal comb is one hundred percent effective employed individuals trained in egg removal to comb patients' hair. According to the complaint, there is no evidence that the same results are achievable by an average consumer.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondent from engaging in similar acts and practices in the future. Part I of the proposed order would prohibit the company from representing that RID Lice Killing Shampoo or any substantially similar product cures a lice infestation in a single application, unless the representation is true and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

Parts II and III of the order require that, for a period of two years, the company make disclosures in its advertisements anytime it makes claims regarding the efficacy of RID or any substantially similar product. Pursuant to Part II, the following disclosure will be required in print ads and promotional materials: "Reapplication and egg removal are required to ensure complete effectiveness. See label for important information." Part III requires the disclosure, "Two Treatments Required," be made in ads communicated through an electronic medium, such as television. When the ad makes any claims regarding directions for use of the product, this disclosure must be in the audio as well as the video portion of the advertisement.

Part IV of the proposed order prohibits Pfizer from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, for any drug or device for the treatment of lice in humans, or any pesticide for treatment of lice. Part V of the proposed order requires the company to have scientific support prior to making any claims regarding the efficacy of any drug or device for the treatment of lice in humans, or any pesticide for treatment of lice. Because this matter involves a drug regulated by the FDA, Part VI of the order includes a safe harbor allowing the respondent to make any claim permitted under a new drug application, or under a tentative final or final standard promulgated by that agency.

The proposed order also requires the respondent to maintain materials relied

upon to substantiate claims covered by the order; to provide copies of the order to certain personnel of the respondent; to notify the Commission of any changes in corporate structure that might affect compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,
Secretary.

Statement of Chairman Pitofsky and Commissioners Anthony and Thompson

In the Matters of, Care Technologies, Inc., File No. 972-3136, Del Pharmaceuticals, Inc., File No. 972-3084, Pfizer Inc., File No. 972-3159.

We write to express our view about the concerns Commissioner Swindle raises regarding the disclosure remedy in these cases. The orders require that, for two years, whenever a claim is made regarding the efficacy of the lice removal products, the respondents include a disclosure about the necessity for a second application of their product. Commissioner Swindle is concerned that this amounts to corrective advertising, and should not be imposed absent evidence that consumers hold lingering misbeliefs.

Unlike corrective advertising that is designed to correct misbeliefs caused by past advertising, the disclosure remedy in these cases in fencing-in relief, designed to prevent purchasers of respondents' products from being deceived by future advertising.¹ The triggered disclosure about the need for two treatments provides additional assurance that consumers will not be misled by future ads. We are satisfied that the triggered disclosures in these orders are appropriate and reasonably related to the alleged violations of Section 5.

Statement of Commissioner Orson Swindle

In the Matters of, Care Technologies, Inc., File No. 972-3136, Del Pharmaceuticals, Inc., File No. 972-3084, Pfizer Inc., File No. 972-3159.

I have voted to accept these consent agreements for public comment despite

¹ It is also worth noting that the Commission has distinguished triggered disclosures such as those in these cases from corrective advertising, which is required regardless of the contents of the ad. *Removatron Int'l Corp.*, 111 F.T.C. 206, 311-12 n. 28 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989). See also *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 700 (3d Cir. 1982).

my reservations about the disclosure requirements. Advertising for these lice treatment products has contained false and misleading claims that the products can eradicate an infestation after a single use. In truth, reapplication and careful combing are required to complete the treatments. I have no doubt that the injunctive provisions are needed and appropriate to address these misrepresentations.

The settlements, however, go further. Under the terms of the consent orders, the respondents would be required for two years to state, in any advertising for lice treatments that makes an efficacy claim, that two applications of the treatment are necessary. The orders would mandate this disclosure in addition to prohibiting the challenged claims and requiring competent and reliable scientific evidence to substantiate any representation about the efficacy of the products.

The disclosures cannot be justified as necessary to correct a deception by omission. The orders prohibit the challenged claims and require substantiation for future claims. Any representation—either express or implied—that only one application will complete the treatment would violate the terms of this order. The disclosures are therefore not necessary to protect against false or misleading claims about the efficacy of a single treatment.

The proposed consent orders in effect require that the respondents include a corrective message in their advertising. We have no evidence that the respondents' marketing substantially created or reinforced a lingering misimpression about these products. *Warner-Lambert Co. v. FTC*, 562 F.2d 749 (D.C. Cir. 1977), cert. denied, 435 U.S. 950 (1978). The disclosure requirement cannot, therefore, be justified as corrective advertising.

Fencing-in relief in a consent order could arguably require that the respondent disseminate information to educate consumers. In these cases, however, I fear that we are using our fencing-in authority to justify what is actually corrective advertising. If we cannot meet the standard for imposing this relief as corrective advertising, let us not try to camouflage it as fencing-in.

I support the Commission's move toward stronger remedies. In this case, the injunctive provisions, together with the FDA-mandated labeling,¹ should

¹ The FDA requires the following statement on the label of any shampoo formulated to treat head lice:

Apply to affected area until all the hair is thoroughly wet with product. Allow product to

ensure that consumers have truthful and accurate information before and after purchase. The disclosure requirement, however, is superfluous and the facts do not justify corrective advertising.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Reallotment of FY 1997 Funds for Low Income Home Energy Assistance Program (LIHEAP)

AGENCY: Office of Community Services, ACF, DHHS.

ACTION: Notice of final determination concerning funds available for reallotment.

SUMMARY: In accordance with section 2607(b)(1) of the Low Income Home Energy Assistance Act, title XXVI of the Omnibus Budget Reconciliation Act of 1981, as amended (42 U.S.C. 8621 et seq.), a notice was published in the **Federal Register** on August 6, 1998 announcing the Secretary's preliminary determination that \$82,025 in FY 1997 Low Income Home Energy Assistance Program (LIHEAP) funds may be available for reallotment to other LIHEAP grantees and offering the State which is the source of funds a period for comments, which closed August 31, 1998. No comments were received.

Therefore, in accordance with the requirements of section 2607(a)(2)(C), \$82,025 will be reallotted to most current LIHEAP grantees based upon the current allocation formula contained in section 2604 of the Act and under the terms of applicable State/Tribe agreements, except that HHS will not issue grants under \$25 because the cost of issuing the grant for that amount is greater than the amount of the grant. These reallotted funds are being distributed by statutory formula to States, Indian Tribes and Tribal organizations, and insular areas that are currently grantees under the LIHEAP program for FY 1998. No other entities may apply for or receive the funds from HHS.

The reallotted funds must be treated by LIHEAP grantees receiving them as

remain on area for 10 minutes but no longer. Add sufficient warm water to form a lather and shampoo as usual. Rinse thoroughly. A fine-toothed comb or special lice/nit removing comb may be used to help remove dead lice or their eggs (nits) from hair. A second treatment must be done in 7 to 10 days to kill any newly hatched lice.