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 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 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.

[FR Doc. 98–25846 Filed 9–25–98; 8:45 am]

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[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).

[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 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.

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

an amount appropriated for FY 1998. As FY 1998 funds, they will be subject to all of the requirements of the Act, including section 2607(b)(2), which requires that a grantee must obligate 90 percent of its total block grant allocation for a fiscal year by the end of the fiscal year for which the funds are appropriated, that is, by September 30, 1998.

FOR FURTHER INFORMATION CONTACT: Janet Fox, Director, Division of Energy Assistance, Office of Community Services, 370 L'Enfant Promenade, SW, Washington, DC 20447; telephone (202) 401–9351.

Dated: September 18, 1998.

Donald Sykes,

Director, Office of Community Services.

[FR Doc. 98–25881 Filed 9–25–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety Risk Assessment Clearinghouse; Postponement of Open Technical Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) are announcing postponement of an open technical workshop on the formation of a Food Safety Risk Assessment Clearinghouse originally scheduled for October 5 and 6, 1998 (63 FR 40530, July 29, 1998). The workshop is being postponed due to scheduling conflicts as well as the need for further research to assure that the technical workshop will be effective at soliciting input into the clearinghouse framework document.

Date and Time: The technical workshop will be rescheduled for early 1999.

Registration: Notification of postponement and the new workshop date will be sent to all preregistered parties. To be automatically notified of the new workshop date, please contact Jacqueline M. Williams, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4224, FAX 202–205–4422, or monitor on-line at ''http://www.life.umd.edu/jifsan/chouse.html''.

FOR FURTHER INFORMATION CONTACT: Valerie M. Davis (FDA) or Roberta Morales, VA–MD Regional College of Veterinary Medicine, University of Maryland, College Park, MD, 20742–3711, 301–935–6083, ext. 158, FAX 301–935–0149.

SUPPLEMENTARY INFORMATION: The May 1997 Report to the President on the National Food Safety Initiative described the need to establish a clearinghouse that would collect and catalogue available data and methodology pertinent to microbial risk-assessment offered by the private sector, trade associations, Federal and State agencies, and international sources. The goals of the clearinghouse would be to consolidate research data and methodology from public and proprietary sources, assist in coordinating research activities, identify gaps in needed research, and assist in the development of microbial risk assessment models.

An open meeting was held on August 7, 1998, which provided an overview of risk assessment, introduced the concept of a risk assessment clearinghouse, and identified and solicited the needs of potential users. Input of potential users from Federal and local government, academia, private industry, and consumer groups in attendance at the meeting are still being evaluated but several general observations are evident: (1) There is widespread interest and support for the clearinghouse among all groups; (2) it is critical to involve interested parties at every stage in the development of the clearinghouse; (3) educational efforts to explain the role of risk assessment in food safety decisionmaking should continue; and (4) the risk assessment clearinghouse must provide access to information in areas of risk management and food safety that would be useful to a broad cross section of users.

Summaries from focus group discussions and raw data collected from the participants in the August 7, 1998, open meeting entitled ''Risk Assessment Clearinghouse: Users and Needs'' will be posted on the World Wide Web (WWW) at ''http://www.life.umd.edu/jifsan/chouse.html''. Those accessing the website will be able to submit further input directly on the website. In addition, the draft clearinghouse framework document, intended to be the focal point of the upcoming technical workshop, will be posted on the WWW at ''http://www.life.umd.edu/jifsan/chouse.html''. Comments are encouraged and input will be accepted directly on the website. The new date and location of this workshop will be announced on the previously mentioned WWW address.

Dated: September 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25794 Filed 9–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 8, 1998, 9:30 a.m. to 6 p.m., and October 9, 1998, 8 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Hany W. Demian, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 8, 1998, the committee will consider issues relating to the study and evaluation of spinal device assemblies. In the context of a preliminary background document entitled ''Guidance Document for the Preparation of IDE's for Spinal Assemblies,'' the committee will be asked to address scientific issues pertaining to the development of investigational device exemptions (IDE's) applications for spinal device assemblies. This will include inclusion/exclusion criteria, type of control(s), study endpoints, and length of followup. Single copies of the preliminary background document are available to the public by contacting the Division of Small Manufacturers