assets in the hands of Schering-Plough are sufficient to replace the lost competition that would result from the acquisition.

Public comments regarding all aspects of the proposed divestiture to Schering-Plough will be considered with other comments on the proposed Order.

Under the proposed Order, if Schering-Plough ceases to sell contract manufactured canine lyme, canine corona virus combination and feline leukemia combination vaccines prior to obtaining USDA certification, abandons its efforts to obtain USDA approval, or fails to obtain timely USDA approval, or in the event AHP fails to divest the assets absolutely and in good faith, the Commission may terminate the divestiture agreement and appoint a trustee to divest Solvay's canine lyme vaccine, canine corona virus combination vaccines, and feline leukemia combination vaccines, as well as Solvay's Charles City Facility and equine vaccines. The crown jewel provision also includes, at AHP's discretion, a supply contract for a term not to exceed (3) three years from the date of the divestiture, which requires the new acquirer to supply AHP (i) any swine or poultry vaccines for sale worldwide, (ii) any canine lyme vaccine, canine corona virus combination vaccines and feline leukemia combination vaccines for sale by AHP outside the United States and Canada and (iii) single antigen rabies vaccine and feline leukemia combination vaccine with rabies for sale worldwide being produced at the Charles City Facility at the time of divestiture, priced at each vaccine's average total cost. This crown jewel provision will ensure that a trustee can divest a package of assets that is sufficiently attractive to potential buyers.

Under the provisions of the proposed Order, AHP is also required to provide the Commission with a report of compliance with the divestiture provisions of the Order within sixty (60) days following the date this Order becomes final, and every ninety (90) days thereafter until AHP has fully complied with the divestiture provisions of the proposed Order.

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

Donald S. Clark,

Secretary.

Concurring Statement of Commissioner Mary L. Azcuenaga in American Home Products Corp., File No. 971–0009

I concur in the decision to accept the consent agreement for public comment and write separately to invite comment on whether and when the Commission should require the firm divesting assets to give up patent rights beyond those acquired in the transaction at issue. Paragraph IID of the proposed order requires American Home Products (AHP) not only to license the intellectual property that is acquired from Solvay S.A., but also to agree not to sue the acquiring firm for infringement of vaccine patents that AHP owned before the acquisition. The firm purchasing the divested assets will obtain Solvay's intellectual property free and clear of any claim that the Solvay vaccines infringe AHP's patents. Should the Commission resolve the patent dispute regarding whether Solvay's vaccines infringed AHP's patents, and if so, how should such a dispute be resolved?

[FR Doc. 97–5343 Filed 3–4–97; 8:45 am]

BILLING CODE 6750–01–M

[File No. 942–3341]

Schering-Plough Healthcare Products, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, the marketer of Coppertone Kids sunscreens for children from making deceptive claims about the effectiveness of sunscreens marketed for use on children. The agreement will also require that the company produce and distribute 150,000 consumer education brochures to alert parents to the importance of sunscreen protection for children and the need to reapply sunscreens after toweling or sustained vigorous activity. The complaint accompanying the consent agreement alleges that Schering's ads for Coppertone Kids 6-Hour Waterproof Sunblock make unsubstantiated claims that one application of Coppertone Kids provides six hours of protection from the sun for children engaged in sustained vigorous activity in and out of the water.

DATES: Comments must be received on or before May 5, 1997.

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

FOR FURTHER INFORMATION CONTACT: Joel Winston, Federal Trade Commission, S–4002, 6th St. and Pa. Ave., N.W., Washington, D.C. 20580. (202) 326–3153; Toby Milgrom Levin, Federal Trade Commission, S–4002, 6th St. and Pa. Ave., N.W., Washington, D.C. 20580. (202) 326–3156.

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 accompanying complaint. An electronic copy of the full text of the consent agreement package can be obtained from the Commission Actions section of the FTC Home Page (for February 18, 1997), on the World Wide Web, at ''http://www.ftc.gov/os/actions/htm.'' A paper copy can be obtained from the FTC Public Reference Room, Room H–130, Sixth Street and Pennsylvania Avenue, N.W., Washington, D.C. 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 to a proposed consent order from Schering-Plough Healthcare Products, Inc. (''Schering-Plough Healthcare''). Schering-Plough Healthcare, a wholly-owned subsidiary of the Schering-Plough Corporation, is a manufacturer and distributor of health care products, including sunscreens.

The proposed consent order has been placed on the public record for sixty (60) days for receipt 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.

This matter involves alleged deceptive representations made in advertising for Coppertone Kids, a sunscreen product promoted for use on children. According to the FTC complaint, Schering-Plough Healthcare represented, without adequate substantiation, that a single application of Coppertone Kids provides six hours of protection from the sun, at the advertised SPF level, for children engaged in sustained vigorous activity in and out of the water. The complaint also alleges that Schering-Plough Healthcare falsely represented that it had conducted tests demonstrating that the product provides such protection. According to the complaint, among other things, the company's tests did not evaluate a single application of the product under the advertised conditions of use (sustained vigorous activity).

The consent order contains provisions designed to remedy the violations charged and to prevent Schering-Plough Healthcare from engaging in similar acts and practices in the future.

Part I of the proposed order prohibits Schering-Plough Healthcare from representing: (a) the length of time that Coppertone Kids or any other children's sun protection product will provide protection from the sun for persons engaged in sustained vigorous activity in and out of the water; or (b) the efficacy of any children's sun protection product in providing protection against any harmful effect of sun exposure or ultraviolet radiation, unless the company has scientific substantiation for the representation.

The order defines a ''children's sun protection product'' as any sun protection product that uses the word ''babies,'' ''children,'' ''kids,'' or other similar words in the name or promotion of the product, or that is advertised or promoted for use primarily on children under the age of twelve.

Part II of the proposed order prohibits Schering-Plough Healthcare from misrepresenting the existence, contents, validity, or conclusions of any test or study concerning any sun protection product.

Part III of the order allows Schering-Plough Healthcare to make any representation for a sun protection product that is specifically permitted in labeling for that product under any tentative final or final Food and Drug Administration standard or under any new drug application approved by the Food and Drug Administration.

Part IV of the proposed order requires Schering-Plough Healthcare to produce and disseminate a consumer brochure addressing the importance of sunscreen usage to children and the health benefits associated with it, and promoting the proper use and application of sunscreens on children. The brochure, which is subject to FTC approval, will be disseminated by Schering-Plough Healthcare to organizations with direct access to parents or organizations with access to parents or others who work with or care for children under the age of 12.

Parts V, VII, IX, and X of the proposed order require Schering-Plough Healthcare to keep copies of all materials relied upon in making any representations covered by Parts I and II of the order; to provide copies of the order to certain of the company's personnel; to notify the Commission of any change in corporate structure; and to file compliance reports with the Commission. Part VI permits respondent to use existing labeling for 100 days after the date of service of the order. Part VIII provides that the order will terminate after twenty (20) years under certain circumstances.

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

Donald S. Clark,

Secretary.

Separate Statement of Commissioner Mary L. Azcuenaga Concurring in Part and Dissenting in Part in Schering-Plough Healthcare, File No. 942 3341

Today, the Commission accepts for public comment a proposed consent agreement resolving allegations about certain claims in the advertising of Coppertone Kids 6-Hour Waterproof Sunblock. I concur except with respect to Part IV of the proposed order, which requires the respondent to develop and disseminate a consumer education brochure addressing the dangers of unprotected exposure to the sun. Consumer education brochures are an integral part of the Commission's consumer protection program, but they are not necessarily defensible adjuncts to Commission orders.

A fencing-in provision will be sustained by the courts as long as it is ''reasonably related'' to the violation found.[1] Fencing-in relief properly may include requirements beyond simply prohibiting the challenged conduct that are designed to ''close all roads to the prohibited goal, so that [the Commission's] order may not be by-passed with impunity.'' [2] The allegedly deceptive claim is that the respondent's sunblock for children would remain effective for six hours even if the children engaged in ''sustained vigorous activities in and out of the water,'' such as playing in sand, taking off and putting on clothes and toweling off after swimming. Complaint ¶5. The proposed order expressly enjoins the respondents from making the challenged claim, either directly or indirectly, for the product at issue as well as for ''any other children's sun protection product.'' Order ¶I.

In addition, the proposed order requires the respondent to develop and distribute 150,000 copies of a color brochure concerning the importance of sunscreen usage by children. The order requires that the brochure contain six messages or themes only one of which addresses the issue in this case, the need to reapply so-called water-proof or water-resistant sunblock after vigorous activity or after toweling off. Order ¶ IV–E.

The brochure requirement, even the message that relates most closely to the challenged claim, is not focused on preventing the respondent from making the challenged claim or otherwise from avoiding compliance with the order. The brochure would help educate consumers regarding an important health issue, and, presumably, make them less likely to be misled by the kind of implied claims challenged in this action.[3] There is no reason to think that it would enhance the deterrent effect of the order on Schering.

Presumably, the brochure requirement will not be unduly burdensome or costly for Schering because it will promote the use of its product, and the brochure is undoubtedly commendable as a public health initiative. Nevertheless, under the circumstances, it is an overly broad order requirement as measured against the current standard for ordering relief.[4] There is a

[1] FTC v. Colgate-Palmolive Co., 380 U.S. 374, 394–95 (1965); FTC v. National Lead Co., 352 U.S. 419, 428 (1957).

[2] FTC v. Ruberoid Co., 343 U.S. 470, 473 (1952).

[3] The product label already contains the statement, ''Reapply after toweling.''

[4] It would be even more difficult to justify Part IV of the order as corrective advertising, because it is unlikely that the implied claim challenged in the complaint would linger in the minds of consumers long after it ceased being made. *See Warner-Lambert Co.* v. *FTC,* 562 F.2d 749, 762 (D.C. Cir. 1977), cert. denied, 435 U.S. 950 (1978).

value to the Commission in maintaining the integrity of the standard for imposing a fencing-in remedy.

I respectfully dissent from Part IV of the order.

Separate Statement of Commissioner Roscoe B. Starek, III Concurring in Part and Dissenting in Part in Schering-Plough Healthcare, File No. 9423341

I have voted to accept for public comment the consent agreement with Schering-Plough Healthcare Products, Inc. (''Schering''), because I have reason to believe that the challenged advertisements are deceptive and I find that the proposed order, for the most part, provides appropriate relief. I do not, however, support the requirement that Schering produce and distribute a consumer education brochure that includes numerous specified ''messages or themes.'' As set forth in the proposed order, this consumer education remedy is overbroad and in any event is unlikely to assist in the prevention of the violations alleged in the complaint. Although I am an advocate of a strong Commission consumer education program, and we can be proud of the valuable work done by the Bureau of Consumer Protection's Office of Consumer and Business Education, this remedy is a well-meaning but not legally justifiable effort to fund a general consumer education campaign.

The Commission enjoys extensive authority to fashion fencing-in relief for deceptive practices so long as the remedy has a reasonable relation to the violations alleged in the complaint. *See, e.g., FTC* versus *Colgate-Palmolive Co.,* 380 U.S. 374, 394–95 (1965); *FTC* versus *National Lead Co.,* 352 U.S. 419, 428–29 (1957). With such authority, however, comes the responsibility to exercise it judiciously. In my view, the consumer education remedy mandated by this proposed order bears no reasonable relationship to the violations alleged in the complaint.

The proposed complaint alleges that Schering lacked a reasonable basis for the claim that a single application of Coppertone Kids provides six hours of protection from the sun for children engaged in sustained vigorous activity in and out of the water.[1] The order addresses this allegation by requiring scientific substantiation for claims about the efficacy of any children's sun protection product in providing protection against any harmful effect of sun exposure or ultraviolet radiation, or about the length of time that any such product will provide sun protection for individuals engaged in sustained vigorous activity in and out of the water.

In addition, however, the order would require Schering to design, produce and print a brochure—subject to the approval of the Associate Director of the Division of Advertising Practices (''DAP'') in the Commission's Bureau of Consumer Protection—about the importance of sunscreen usage by children. The order mandates that the brochure include all of the following ''messages or themes'':

(A) The importance of sunscreens in preventing skin damage, including skin cancer, sunburn, and premature skin aging;

(B) Regular use of a high SPF sunscreen during childhood can significantly reduce the risk of certain types of skin cancers later in life;

(C) A single bad sunburn during childhood can significantly increase a child's risk of developing skin cancer later in life;

(D) The importance of proper application of sunscreens;

(E) The need to reapply sunscreens after toweling or sustained vigorous activity; and

(F) The need to use sunscreens during outdoor activities—not only in connection with water activities.

Order ¶ IV. The respondent must disseminate 150,000 copies of this brochure to parents or to organizations with access to parents or others who work with or care for children under age twelve.[2]

Of the six required messages, only statement (E) seems likely to assist in the prevention of future deception like or related to that alleged in the complaint. Yet by including this key reapplication information in an extensive list of other facts about sunscreen, the order makes it less likely that consumers will see the reapplication information. In my view, it is highly unlikely that a parent who receives and reviews whatever brochure is approved will recall the one piece of information related to the complaint allegation when the parent makes a sunscreen purchase. Because the scope of the information to be included in the brochure is so broad, the consumer education remedy is not reasonably related to the violations alleged in the proposed complaint.[3]

It is also troubling that if the Commission issues this order, it essentially will be ordering the respondent to advertise that persons should buy and use more of the respondent's products. Schering already has every incentive to communicate the required messages to consumers. In fact, the consumer education remedy is advertising (''use more sunscreen'') that the company might wish to do in any event since the conduct provisions of the order may prevent it from continuing to distinguish its children's sun protection product from others by claiming that it requires fewer applications. The deterrence value of this remedy is minimal at best.

Finally, if this relief were sought in litigation, rather than obtained through a consent agreement, it would not withstand scrutiny under the First Amendment. For purposes of First Amendment analysis, there is no difference between compelled speech and restrictions on speech. *Riley* v. *National Fed'n of the Blind,* 487 U.S. 781, 796–97 (1988). A valid restriction on commercial speech must be no more extensive than necessary to serve the substantial governmental interest directly advanced by the restriction. *Rubin* v. *Coors Brewing Co.,* 115 S. Ct. 1585, 1591 (1995) (discussing *Central Hudson Gas & Elec. Corp.* v. *Public Serv. Comm'n of N.Y.,* 447 U.S. 557, 566 (1980)). Thus, disclosures compelled by the FTC can be no broader than necessary to prevent future deception or to correct the effects of past deception. *See, e.g., National Comm'n on Egg Nutrition* v. *FTC,* 570 F.2d 157, 164 (7th Cir. 1977), *cert. denied,* 439 U.S. 821 (1978). Additionally, the government bears the burden of showing that a speech restriction will advance its

[1] The proposed complaint challenges as false the claim that Schering has conducted tests demonstrating that a single application of Coppertone Kids provides six hours of protection from the sun for children engaged in sustained vigorous activity in and out of the water. The proposed order broadly prohibits false establishment claims for any sun protection product.

[2] Like the brochure, the dissemination plan is subject to the approval of the Associate Director in charge of DAP.

[3] The consumer education remedy here stands in contrast to a fencing-in provision contained in a consent order issued by the Commission last year. See Blenheim Expositions, Inc., Docket No. C–3633 (Jan. 18, 1996) (requiring a franchise show promoter to undertake a limited distribution of an FTC consumer education brochure to customers attending its franchise shows). The respondent in Blenheim allegedly made unsubstantiated claims regarding the earnings and success of franchise owners and false claims regarding a poll of franchise owners. The brochure specifically identified FTC requirements with which franchisors must comply, including consumers' right to receive an earnings claims document, and it provided instructions on how to evaluate earnings claims. It thus contained information likely to assist the respondent's customers to detect and protect themselves from possible future misrepresentations of earnings like those alleged in the complaint. Although the brochure also addressed other issues related to the purchase of a franchise, all of the advice in the brochure at least arguably would help prospective franchisees avoid becoming victims of future violations by the respondent.

interest ''to a material degree.'' *44 Liquormart, Inc.* v. *Rhode Island,* 116 S. Ct. 1495, 1509 (1996) (plurality opinion of Justice Stevens) (citing *Edenfield* v. *Fane,* 507 U.S. 761, 771 (1993)). A commercial speech restriction that ''provides only ineffective or remote support for the government's purpose'' does not pass this test. *44 Liquormart,* 116 S. Ct. at 1509 (citing *Central Hudson,* 447 U.S. at 564).

The dubious efficacy of the proposed consumer education remedy makes it unlikely that it will directly advance the asserted governmental interest in preventing future deception by the respondent. In addition, I doubt that a credible argument can be made that the information that the order specifically requires be included in the brochure is no more extensive than necessary to prevent future violations by Schering. Certainly Schering has waived any First Amendment objections to this relief by entering into the consent agreement. Nonetheless, when a remedy implicates First Amendment rights, the Commission should be particularly reluctant to obtain through negotiations relief that it lacks at least a colorable chance to obtain in litigation.

In my view, it would be better to have no consumer information remedy in the consent order if the only alternative is an overbroad remedy of doubtful efficacy that raises First Amendment concerns.

[FR Doc. 97–5344 Filed 3–4–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering Laboratory Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Idaho National Engineering Laboratory Health Effects Subcommittee (INEL).

Times and Dates: 8:30 a.m.–5 p.m., March 20, 1997. 8:30 a.m.–5 p.m., March 21, 1997.

Place: Red Lion Inn-Riverside, 2900 Chinden Boulevard, Boise, Idaho 83714, telephone 208/343–1871, FAX 208/344–1079.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The Subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. Activities shall focus on providing a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include presentations from the National Center for Environmental Health (NCEH) regarding current activities, the National Institute for Occupational Safety and Health, and ATSDR will provide updates on the progress of current studies, and working group discussions. Additional presentations will include prioritization and screening of chemicals for INEL dose reconstruction, discussions of screening methodology, and future dose reconstruction activities.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Arthur J. Robinson, Jr., or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–5400 Filed 3–4–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 95N–0329]

Preclearance of Promotional Labeling; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Biologics Evaluation and Research (CBER) is clarifying its policy regarding the preapproval of promotional labeling for biological products. In the November 1995 report issued by the President and Vice President, ''Reinventing the Regulation of Drugs Made from Biotechnology,'' FDA made a commitment to harmonize immediately CBER's requirements for the preapproval of promotional labeling with those of the Center for Drug Evaluation and Research (CDER) under which a company may submit such information to the agency at the time the company disseminates it. This notice is issued to clarify that FDA has fulfilled the commitment to allow industry to submit promotional labeling to CBER at the time of initial dissemination. Sponsors need not wait for approval from CBER before using promotional labeling.

FOR FURTHER INFORMATION CONTACT: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–202), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028.

SUPPLEMENTARY INFORMATION: Under CBER's previous policy, as announced in the Federal Register of August 9, 1993 (58 FR 42340) and revised in the Federal Register of August 3, 1994 (59 FR 39570), preapproval by CBER was required for promotional labeling prior to introduction of a new biologic, for 120 days following approval of a new biologic, and for 120 days following approval of a new use for a currently licensed biologic. In the November 1995 report issued by the President and Vice President, ''Reinventing the Regulation of Drugs Made from Biotechnology,'' FDA made a commitment that, effective immediately, CBER would no longer require preapproval of promotional labeling. This approach, it was noted, is consistent with that of CDER. FDA has fulfilled its commitment.

In a proposed rule on changes to an approved application, published in the Federal Register of January 29, 1996 (61 FR 2739), FDA took a further step toward harmonizing the two Centers' promotional requirements. Among other things, the proposed rule would amend 21 CFR 601.12 to make CBER requirements for advertisements, as well as promotional labeling, consistent with those of CDER as set forth in 21 CFR 314.81(b)(3)(i).

The scope of this notice does not extend to promotional materials for products reviewed under the regulations for accelerated approval (21 CFR part 601, subpart E), which should be submitted to the agency for consideration as required in 21 CFR 601.45.

Dated: February 28, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–5311 Filed 3–4–97; 8:45 am]

BILLING CODE 4160–01–F