ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''Act''), 42 U.S.C. 7413(g), notice is hereby given of a proposed consent decree which was lodged with the United States District Court for the Northern District of California by the United States Environmental Protection Agency (''EPA'') on January 15, 2002 to address a lawsuit filed by the Medical Alliance for Healthy Air, Sierra Club, Latino Issues Forum and Center on Race, Poverty and the Environment, a project of the California Rural Legal Assistance Foundation. This lawsuit, which was filed pursuant to section 304(a) of the Act, 42 U.S.C. 7604(a), addresses EPA's alleged failure to meet mandatory deadlines under section 110(k) of the Act, 42 U.S.C. 7410(k), to take final actions to approve or disapprove the 1997 PM–10 Attainment Demonstration Plan for the San Joaquin Valley (''SJV'') in California and six individual rules for the control of PM–10 and nitrogen oxide (NO_X) in the SJV. *Medical Alliance for Healthy Air et al.* v. *EPA,* Case No. C–01–4086 JCS (N.D. Cal.).

DATES: Written comments on the proposed consent decree must be received by March 27, 2002.

ADDRESSES: Written comments should be sent to Jan Taradash, Office of Regional Counsel, U.S. Environmental Protection Agency Region 9, 75 Hawthorne Street, San Francisco, CA 94105. Copies of the proposed consent decree are available from Jan Taber, (415) 972–3900.

SUPPLEMENTARY INFORMATION: The Clean Air Act requires EPA to take action to approve or disapprove a State implementation plan revision within 12 months of a determination by the Administrator that such revision is complete. See section 110(k)(1)–(4), 42 U.S.C. 7410(k)(1)–(4). In 1997, the California Air Resources Board (''CARB'') submitted to EPA the PM–10 Attainment Demonstration Plan (''1997 Plan'') for the SJV as a proposed revision to the California State Implementation Plan (''SIP''). This SIP revision was deemed complete by operation of law in 1998 pursuant to section 110(k)(1)(B), 42 U.S.C. 7410(k)(1)(B). The proposed consent decree provides that the Administrator or her delegatee shall sign no later than March 1, 2002, a notice for publication in the **Federal Register** proposing action on the 1997 Plan and shall sign no later than August 16, 2002 a notice for publication in the **Federal Register** taking final action pursuant to section 110(k) of the Act, 42 U.S.C. 7410(k).

From 1993 through 1998, CARB also submitted six rules adopted by the San Joaquin Valley Unified Control District for the control of PM–10 and NO_X in the SJV and EPA found them to be complete pursuant to section 110(k)(1)(B), 42 U.S.C. 7410(k)(1)(B) as follows: Rules 4201 (1992), 4901 (1994), 4351 (1996), 4305 (1997), 4701 (1998) and 4703 (1998). EPA has proposed action on these rules pursuant to section 110(k) of the Act, 42 U.S.C. 7410(k). The proposed consent decree provides that the Administrator or her delegatee shall sign no later than January 15, 2002, a notice or notices for publication in the **Federal Register** taking final action on Rules 4901, 4351, 4305, 4701 and 4703 and shall sign such a notice taking final action on Rule 4201 no later than April 7, 2002. The Administrator signed notices by January 15, 2002, taking final action on Rules 4901, 4351, 4305, 4701 and 4703.

For a period of thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the proposed consent decree from persons who were not named as parties to the litigation in question. EPA or the Department of Justice may withhold or withdraw consent to the proposed consent decree if the comments disclose facts or circumstances that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines, following the comment period, that consent is inappropriate, the final consent decree will then be executed by the parties.

Dated: February 15, 2002.

Alan W. Eckert,

Associate General Counsel, Air and Radiation Law Office.

[FR Doc. 02–4404 Filed 2–22–02; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL TRADE COMMISSION

[Docket No. 9297]

American Home Products Corp.; 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 complaint previously issued 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 March 15, 2002.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: *consentagreement@ftc.gov,* as prescribed below.

FOR FURTHER INFORMATION CONTACT: David Pender, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–2549.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and §3.25(f) of the Commission's rules of practice, 16 CFR 3.25(f), 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 thirty (30) 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 February 19, 2002), on the World Wide Web, at ''*http://www.ftc.gov/os/2002/02/index.htm.*'' A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled ''confidential.'' Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to e-mail messages directed to the following e-mail box: *consentagreement@ftc.gov.* Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with §4.9(b)(6)(ii)

of the Commission's rules of practice, 16 CFR 4.9(b)(6)(ii)).

Analysis To Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with American Home Products Corporation. The proposed consent order would settle charges that AHP unlawfully agreed with Schering-Plough Corporation to delay selling its generic version of Schering's K-Dur 20, in exchange for payments from Schering. The proposed consent order has been placed on the public record for 30 days to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by AHP that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true. In July 2001, AHP advised its customers that it intends to phase out its oral generic drug product line.

Background

Schering develops and markets brand name and generic drugs, as well as over-the-counter health care and animal care products. Schering manufactures and markets an extended-release micro-encapsulated potassium chloride product, K-Dur 20. K-Dur 20, marketed as a brand name drug, has sales over $200 million per year. K-Dur 20 is used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems.

AHP develops and markets brand name and generic drugs, as well as over-the-counter medications. ESI Lederle, Incorporated, a division of AHP, received tentative approval from the Food and Drug Administration in May 1999 for a generic version of Schering's K-Dur 20.

Upsher-Smith Laboratories, Inc. develops and markets brand name and generic drugs. Upsher-Smith received final approval from the Food and Drug Administration in November 1998 for a generic version of Schering's K-Dur 20.

Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. A Congressional Budget Office Report estimates that purchasers saved an estimated $8–10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the brand name product. [1]

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as ''the Hatch-Waxman Act,'' establishes certain rights and procedures in situations where a company, such as AHP or Upsher, seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand name drug upon which the generic is based. In such cases, the applicant must: (1) Certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a ''paragraph IV certification''); and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days of the notification, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed. This automatic 30-month stay allows the patent holder time to seek judicial protection of its patent rights before a generic competitor is permitted to market its product.

In addition, the Hatch-Waxman Act provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge invalid patents or design around valid ones. The Act, as currently interpreted, grants the first company to file an ANDA in such cases a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. No other generic manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired.

Upsher-Smith was the first company to file an ANDA for a generic version of Schering's K-Dur 20. Upsher-Smith filed a paragraph IV certification with the FDA, stating that its product did not infringe any valid patent held by Schering covering K-Dur 20. In 1995, Schering sued Upsher-Smith for patent infringement. The complaint alleges that at all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked. Pursuant to the Hatch-Waxman Act, Upsher-Smith was eligible for the right to a 180-day Exclusivity Period for the sale of a generic version of K-Dur 20. The complaint further alleges that as a result, no company could obtain final FDA approval of an ANDA to market or sell a generic version of K-Dur 20 until 180 days after Upsher-Smith first sold its product, or until Upsher-Smith's exclusivity right is relinquished, forfeited or otherwise expired.

ESI was the second company to file an ANDA for K-Dur 20. ESI also filed a paragraph IV certification with the FDA stating that its product did not infringe any valid patent held by Schering covering K-Dur 20. In 1996, Schering sued ESI for patent infringement.

The Challenged Agreements

The complaint challenges unlawful agreements between Schering and Upsher-Smith and among Schering, AHP and ESI to delay the entry of low-cost generic competition to Schering's highly profitable prescription drug K-Dur 20. According to the complaint, when confronted with the prospect of competition to K-Dur 20 through generic entry by Upsher-Smith and ESI, Schering entered into these agreements that kept Upsher, ESI and all other potential generic competitors out of the market. The complaint alleges that the Upsher-Smith/Schering agreement delayed the start of Upsher-Smith's 180-day Exclusivity Period until September 2001 and, as a result, the entry of competition from other generic manufacturers until March 2002.

With respect to AHP and ESI, the complaint alleges that in January 1998, Schering, AHP, and ESI reached an agreement to settle their patent litigation. Pursuant to that agreement: Schering agreed to pay ESI up to $30 million; AHP and ESI agreed to refrain from marketing the allegedly infringing generic version of K-Dur 20 or any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until January 2004; AHP and ESI agreed to refrain from marketing more than one generic version of K-Dur 20 between January 2004 and September 2006, when the K-Dur 20 patent will expire; and AHP and ESI agreed not to conduct, sponsor, file or support a study of the bio-equivalence of any product to K-Dur 20 prior to September 2006. Schering agreed to pay ESI $5 million up front; an additional $10 million if ESI could demonstrate that its generic version of K-Dur 20 was able to be approved by the FDA under an ANDA on or before June 30, 1999; and another $15 million for licenses to two generic products that ESI was developing.

The complaint further alleges that the patent litigation between Schering and ESI was dismissed. Schering has paid ESI over $20 million and continues to make payments under the terms of their agreement. Schering has made no sales to date of the two products it licensed from ESI.

[1] Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry at xiii, 13 (July 1998).

Competitive Analysis

Generic drugs can have a swift marketplace impact, because pharmacists generally are permitted, and in some instances are required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directs otherwise. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (e.g., state Medicaid programs and many private health plans) encourage or insist on the use of generic drugs wherever possible.

The complaint charges that the challenged agreement among Schering, AHP and ESI injured competition by preventing or discouraging the entry of generic K-Dur 20. The complaint also alleges that by making cash payments to ESI, Schering induced it to agree to delay launching its generic version of K-Dur 20. According to the complaint, absent those payments, ESI would not have agreed to delay its entry for so long. The complaint charges that by making cash payments to ESI, Schering protected itself from competition from ESI until 2004. The complaint also alleges that without lower-priced generic competition from Upsher-Smith and ESI, consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others are forced to purchase Schering's more expensive K-Dur 20 product.

The Proposed Order

The proposed order is designed to remedy the unlawful conduct charged against AHP in the complaint and prevent recurrence of such conduct. As described more fully below, the proposed order would essentially prohibit two categories of conduct:

- Agreements in which the NDA holder makes payments to an ANDA filer and the ANDA filer agrees not to market its product for some period of time (except in certain limited circumstances) (Paragraph II deals with agreements that resolve a patent infringement dispute and Paragraph IV covers ''interim'' agreements that apply during the pendency of ongoing patent litigation); and
- Agreements between the NDA holder and an ANDA filer in which the generic competitor agrees not to enter the market with a non-infringing generic product (Paragraph III).

The proposed order would apply to AHP whether it is acting as potential generic competitor (an ANDA filer) or as a branded drug seller (an NDA holder). As noted above, AHP has advised its customers that it intends to phase out its oral generic pharmaceutical product line. It will continue to develop, manufacture, and market brand name drugs and injectable generic drugs. Notwithstanding AHP's plans to phase out its oral generic products—the line of business that includes its generic version of K–Dur 20—an order is appropriate here to prevent a recurrent violation.

Paragraph II of the order covers agreements to resolve patent infringement disputes. It bars agreements wherein (1) The NDA holder makes payments or otherwise transfers something of value to the ANDA filer and (2) the ANDA filer agrees not to market its product for some period of time, except under certain limited circumstances described below. The ban in Paragraph II includes not only settlements of ongoing patent infringement litigation, but also agreements resolving claims of patent infringement that have not resulted in a lawsuit (see Paragraph I.O.). In addition, by virtue of the definition of ''Agreement'' in Paragraph I.D., the order makes it clear that the prohibition on payments for delayed generic entry would cover such arrangements even if they are achieved through separate agreements (for example, where one agreement resolves the patent infringement dispute and another provides for the payment for delayed entry).

The order prohibits not merely cash payments to induce delayed entry, but, more broadly, agreements in which the NDA holder provides something of value to the potential generic entrant, and the ANDA filer agrees in some fashion not to sell its product. Although all of the pharmaceutical agreements that the Commission has challenged to date have involved cash payments, a company could easily evade a prohibition on such agreements by substituting other things of value for cash payments. Thus, to protect against a recurrent violation, the order is not limited to cash payments.

The proposed order distinguishes between the first ANDA filer (the party eligible for the 180-day market exclusivity period under the Hatch-Waxman Act) and later filers. It bars giving ''anything of value'' to the first ANDA filer, but would permit NDA holders to grant other ANDA filers a delayed license to manufacture the ANDA product. The proposed order makes this distinction because an agreement by a later filer to refrain from entering does not block entry by other potential competitors. Where the only value granted by the NDA holder is the license to sell the ANDA product, there is no payment to distort the generic's incentive to seek the earliest possible entry date. In the case of the first ANDA filer, however, any agreement with an NDA holder that involves a promise by the generic firm not to enter the market risks blocking entry by other potential generic competitors, and therefore such agreements are subject to the general prohibition of Paragraph II of the proposed order.

As noted above, the proposed order would create a limited exception to Paragraph II's ban on giving value for delayed entry. This exception addresses the possibility that there might be some agreements that fall within the terms of the prohibition in Paragraph II that the Commission would not wish to prohibit. For example, as was previously discussed, the proposed order would ban not only agreements involving cash payments of the type that the Commission has challenged to date, but also the giving of other things of value. It is possible, however, that the giving of some non-cash items in a settlement that did not provide for immediate entry by the ANDA filer could promote competition. Thus, the order includes a mechanism that would permit consideration of such arrangements.

The exception that has been crafted in this matter could arise only in situations where Respondent AHP presents the agreement to a court in connection with a joint stipulation for a permanent injunction. In that circumstance, Paragraph II will not bar an otherwise prohibited agreement, if the following conditions are met:

- First, Respondent must follow certain procedures designed to provide notice and information both to the Commission and the court: (1) Along with the joint stipulation for permanent injunction and the proposed agreement, Respondent must provide the court with a copy of the Commission's complaint, order, and the Analysis to Aid Public Comment in this matter; (2) at least 30 days before submitting the stipulation to the court, Respondent must provide written notice (as set forth in Paragraph V of the order) to the Commission; and (3) Respondent may not oppose Commission participation in the court's consideration of the request for permanent injunction; and
- Second, either: (1) The court issues a permanent injunction and the parties' agreement conforms to the court's permanent injunction order; or (2) the Commission determines that the agreement does not raise issues under section 5 of the FTC Act.

The proviso to Paragraph II also makes it clear that the order would not

prevent Respondent AHP from unilaterally seeking relief from the court. The proviso sets forth conditions under which AHP could seek to avoid, though court action, the bar on agreements that is set forth in the core prohibition of Paragraph II of the proposed order. These conditions would not affect AHP's ability to take action that did not involve an agreement otherwise prohibited in Paragraph II.

The Commission recognizes that, outside of the class action context, final settlements between private litigants ordinarily are not scrutinized by courts. Unlike the case of a court-ordered preliminary injunction based on a stipulation of the parties (the situation addressed in Paragraph IV, discussed below), the court in the final settlement context has no express legal mandate to consider the public interest. Thus, there remains some degree of risk that an anticompetitive agreement could escape the prohibition of Paragraph II if the parties were able to persuade a court to issue their agreement as a permanent injunction. On the other hand, it is also relatively rare for courts in ordinary private litigation to issue settlement agreements as permanent injunction orders. This is likely to reduce the risk that an anticompetitive agreement would evade the order, because, as noted above, the exception to the prohibitions of Paragraph II does not arise unless the court issues a permanent injunction order. On balance, in light of all the circumstances of this proposed consent order (including that it is the first involving a challenge to a final settlement with a second ANDA filer), the Commission believes that the exception contained in Paragraph II is appropriate here.

Paragraph III prohibits agreements between an NDA holder and an ANDA filer in which the ANDA filer agrees not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The Commission has previously considered this type of restraint in the context of an agreement between an NDA holder and an ANDA first filer (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity), and had limited the bans in previous orders to that context. Having now considered a similar restraint in an agreement involving a later ANDA filer, the Commission believes it is appropriate to extend this prohibition to agreements between an NDA holder and any ANDA filer.

Paragraph IV addresses what are sometimes referred to as interim settlement agreements. It covers agreements that involve payment to an ANDA filer and in which the ANDA filer agrees not to enter the market for a period of time, but the patent infringement litigation continues. AHP would be barred from entering into such interim agreements. As in Paragraph II, it extends beyond cash payments to cover the NDA holder's providing ''anything of value'' to the ANDA filer, and provides an exception in limited circumstances, similar to those described in connection with Paragraph II of the proposed order. Although the challenged conduct here was an agreement in connection with a final settlement of litigation, rather than an interim agreement, this provision is appropriate in light of the serious antitrust concerns raised by interim agreements and the need to impose an order to prevent recurrence of violations similar to that with which AHP is charged.

The form of notice that Respondent AHP must provide to the Commission under Paragraphs II and IV of the order is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, AHP is required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the order requires Respondent to identify, among other things, all others known by AHP to have filed an ANDA for a product containing the same chemical entities as the product at issue, as well as the court that is hearing any relevant legal proceedings involving Respondent. In addition, Respondent AHP must provide the Commission with certain documents that evaluate the proposed agreement.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The proposed order would expire in 10 years.

Opportunity for Public Comment

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make the proposed order final.

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

By direction of the Commission, Chairman Muris not participating.

Donald S. Clark,

Secretary.

[FR Doc. 02–4374 Filed 2–22–02; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 992 3034]

TechnoBrands, Inc., et al.; 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 March 30, 2002.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW,. Washington, DC 20580. Comments filed in electronic form should be directed to: *consentagreement@ftc.gov,* as prescribed below.

FOR FURTHER INFORMATION CONTACT: James Dolan or Heather Hippsley, Bureau of Consumer Protection, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–3292 or 326–3285.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 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 thirty (30) 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 February 19, 2002), on the World Wide Web, at *http://*