modem or similar device that in most cases must be connected to a land telephone line or a mobile telephone; and moreover, many mobile telephones currently in use in the United States are not compatible with the Jornada Pocket PC. The complaint also alleges that in representing that consumers can use the Jornada to access the Internet and their email accounts, at anytime and from anywhere, respondent failed to disclose or failed to disclose adequately that in order to access remotely the Internet and their email accounts, consumers must purchase and carry a separate modem or similar device. The complaint alleges that the failure to disclose this material fact is a deceptive practice.

The proposed consent order contains provisions designed to prevent HP from engaging in similar acts and practices in the future. Specifically, Parts I and II address representations regarding any PDA or handheld Internet or email access device that requires the use of an additional device or connection to a telephone land line in order to access the Internet or email accounts remotely (''covered devices'').

Part I of the proposed order prohibits respondent from making any misrepresentations about the ability of any covered device to access the Internet or email accounts, or about any performance characteristic of any covered device affecting access to the Internet or email accounts.

Part II of the proposed order prohibits respondent from making any representation about the ability of any covered device to access the Internet or email accounts unless respondent discloses, clearly and conspicuously, any other products (such as a modem, mobile telephone, or adapter) or Internet or email access services (other than general-purpose ISP service, as defined in the order) that consumers must purchase in order to access the Internet or email accounts.

Parts III through VI of the order require HP to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part VII 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.

By direction of the Commission.

Donald S. Clark,

Secretary.

Concurring Statement of Commissioner Orson Swindle

I voted to accept both of these consent agreements for public comment, because the proposed consent orders are adequate relief for the violations alleged in the complaint. Nonetheless, I have strong reservations about the use of unenforceable ''voluntary'' consumer education. In each of these cases, staff negotiated with the proposed respondent to achieve a consumer education campaign that is being undertaken wholly outside the confines of the order. Consumer education remedies sometimes pose difficult issues and Commissioners may disagree as to whether a particular consumer education remedy is appropriate and reasonably related to the complaint allegations. Yet the solution for such disagreements is not simply to excise such remedies from the legally enforceable obligations that respondents are undertaking in settlement. If consumer education is important enough to include in negotiations, there likely is some impact on what is achieved in negotiating the terms of consent order itself. Moreover, to the extent that the FTC promotes such ''voluntary'' consumer education initiatives in our efforts to publicize the consent agreements, we may see many more deep-pocketed respondents seeking to add a bit of ''voluntary;'' and unenforceable consumer education to a broader promotional campaign in exchange for a weaker order than might otherwise be negotiated.

[FR Doc. 01–8708 Filed 4–9–01; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[Docket No. 9293]

Hoechst Marion Roussel, 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 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 May 2, 2001.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Markus Meier or Richard Feinstein, FTC/S–3115, 600 Pennsylvania Ave., NW., Washington, DC 20580. (202) 326–3759 or 326–3688.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and section 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 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 April 2, 2001), on the World Wide Web, at ''http://www.ftc.gov/os/2001/04/index.htm.'' A paper copy can be obtained from the FTC Public Reference Room, Room H–130, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, DC 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible by a 3½ inch diskette containing an electronic copy of the comment. 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 To Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Hoechst Marion Roussel, Inc. (''HMR''), Carderm Capital, L.P. (''Carderm''), and Andrx Corporation (''Andrx'') to resolve the matters alleged in an administrative complaint issued by the Commission on March 16, 2000. The proposed consent order has been placed on the public record for 30 days to receive comments from interested members of the public. The proposed consent order has been entered into for

settlement purposes only and does not constitute an admission by HMR, Carderm, or Andrx (collectively ''the Respondents'') that they violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true. Respondents deny all other allegations of the complaint.

The Complaint

The complaint alleges that the Respondents entered into an agreement that had the tendency or capacity to restrain competition unreasonably by discouraging generic competition to Cardizem CD. Cardizem CD is a prescription drug manufactured and sold by HMR and is used to treat two chronic conditions that affect millions of Americans: hypertension (high blood pressure) and angina pectoris (chest pain). Andrx is a generic drug manufacturer that developed a generic version of Cardizem CD.

Generic drugs typically are sold at substantial discounts from the price of branded drugs. Generic drugs can have a swift marketplace impact, the complaint states, 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.

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as ''the Hatch-Waxman Act,'' to facilitate the entry of lower priced generic drugs while maintaining incentives to invest in new drug development. A company seeking approval from the Food and Drug Administration (''FDA'') to market a new drug must file a New Drug Application (''NDA'') demonstrating the safety and efficacy of its product. In order to receive FDA approval to market a generic version of a brand name drug a company must file an Abbreviated New Drug Application (''ANDA'') demonstrating that its product is bioequivalent to its brand-name counterpart.

The Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic drug prior to the expiration of a patent or patents relating to the brand name drug upon which the generic is based. In such Ame952 -1.1111sshes

quarterly payments of $10 million to Andrx.

Andrx filed a supplement to its ANDA reflecting a reformulation of its generic Cardizem CD product in September 1998. This reformulation altered the dissolution profile of the Andrx product, which was the basis of the patent dispute between Andrx and HMR. The FDA required Andrx to file a new certification and give notice to HMR of the reformulated product under the Hatch-Waxman procedures described above. Following its analysis of the reformulated product, HMR agreed that it would not assert a patent claim against the reformulated product. By June 1999, Andrx had solved the difficulties it had encountered since the summer of 1997 in consistently manufacturing commercial scale quantities of its formulations of its product in conformity with FDA regulations. Andrx received FDA approval in June 1999 to market its reformulated version of Cardizem CD. On or about the day Andrx received FDA approval of its reformulated product, the Respondents entered into a stipulation dismissing the litigation, with an agreement by Andrx not to sell its original formulation and an agreement by HMR not to sue Andrx for patent infringement on Andrx's reformulated product. The challenged agreement terminated.

On or about June 23, 1999, the federal district court dismissed the patent suit, and Andrx commenced marketing its reformulated generic Cardizem CD product, triggering its 180-day exclusivity period. At that time, Biovail Corporation International had not received tentative FDA approval for its product, and Purepac Pharmaceutical Co. had entered into a licensing arrangement with HMR for manufacture of generic Cardizem CD. Andrx's 180-day exclusivity period expired on December 19, 1999. Purepac launched its generic Cardizem CD product the next day pursuant to a license from HMR. Biovail obtained final FDA approval on December 23, 1999, and launched its product shortly thereafter.

Based on the FTC's investigation, it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD. The agreement terminated in June 1999. It was at that time that Andrx received FDA approval to market, and commenced marketing, a reformulated generic version of Cardizem CD that HMR stipulated did not infringe any HMR patent.

The complaint alleges that the challenged agreement was not justified by countervailing efficiencies. In its complaint, the Commission alleged that the presence in the agreement of a licensing provision (permitting Andrx to obtain a license from HMR to market generic Cardizem CD in January 2000, in the event Andrx lost the patient litigation, or if another generic company obtained final FDA approval) did not justify the agreement. The complaint that entry by Andrx under a license, had it occurred, likely would have been later than entry by Andrx or another generic manufacturer absent the agreement.

Finally, the complaint charges that HMR had a monopoly in the market for once-a-day diltiazem, and, that by entering into the agreement with Andrx, HMR sought to preserve its dominance by delaying the entry of Andrx and other generic companies into the market. At the time of the challenged agreement, HMR accounted for 70% of the sales of once-a-day diltiazem in the United States. Other drugs, the complaint alleges, are not effective substitutes for once-a-day diltiazem because they are different in efficacy and side effects, and because of risks associated with switching patients from one treatment to another. In addition, the complaint alleges that HMR and Andrx conspired to monopolize the market for once-a-day diltiazem products. The complaint alleges that HMR and Andrx acted with specific intent that HMR monopolize the market for once-a-day diltiazem, and entered into a conspiracy to achieve that goal. Finally, the complaint charges that the Respondents' agreement otherwise amounts to an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Order

In a statement issued at the time of the filing of the complaint in this matter, the members of the Commission stated that cases like this one ''must be examined with respect to [their] particular facts,'' and that the ''development of a full factual record in the administrative proceeding * * * will help to shape further the appropriate parameters of permissible conduct in this area, and guide other companies and their legal advisors.'' [1] Although the particular agreement challenged in the complaint has been terminated, the Commission believes prospective relief is necessary to prevent a recurrence of the types of agreements covered by the proposed order. Private agreements in which the brand name drug company (the ''NDA Holder'') pays the first generic to seek FDA approval (the ''ANDA First Filer''), and the ANDA First Filer agrees not to enter the market, have the potential to delay generic competition and raise serious antitrust issues. Moreover, the FDA has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to a brand name company from extending its monopoly increasingly exceed the potential economic gains to the generic applicant from its 180 days of market exclusivity.[2]

The proposed order strikes an appropriate balance, on a prospective basis, between the legitimate interests of the Respondents and the Commission

[1] Statement of Chairman Pitofsky, Commissioner Anthony, Commissioner Thompson, Commissioner Swindle, and Commissioner Leary concerning Abbott Laboratories and Geneva Pharmaceuticals, Inc., File No. 981–0395 (March 16, 2000).

[2] FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42882–83 (August 6, 1999).

the ANDA First Filer (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity). Paragraph II.A. bars agreements in which the first company to file an ANDA agrees with the NDA Holder not to relinquish its right to the 180-day exclusivity period (as interpreted by the courts at the time of the agreement). Paragraph II.B. prohibits the ANDA First Filer from agreeing not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The order recognizes, however, that even these types of agreements, in the context of certain licensing arrangements, might not raise competitive concerns. Accordingly, conduct otherwise falling within the conduct described in Paragraph II would not be prohibited where the ANDA First Filer agrees to license and introduce a competitive product to the market, its 180-day exclusivity right is

not extended, and ... ductet ylucensibie8d not be pr an*(Pa1TD(ever,ightph IccocmhF16 1 Tf5.55037 0 TD0 Tw()Tj/F20 1 Tf0

competitive concerns ... fies pars of the(nsAosbee orderiee)Tj-10 -1.1 TD deigntedtn enhanic (the(courcocmhF16 1 Tf13.7587

ns agreement, ... Paragraph IV ... agreements in which the ANDA First Filer agrees with the NDA Holder fro

)A which noe ltigatnc0ehaee

the(coure and)TjT*embodibed inae(cour- ordebef)TjT*p relminary injunctnc0r, and(b)A the

conitnc0s,aeremet:d(i)d

loing wit panystipulatnc0sforf

agreement. Ssich not bdwill, esgis the

otmenialsforf

mydcreatbe Abesni, the orde, theremmye

agreement. pr an*(Pa1TD(e-0.0045 TwTthenorme of not bd that the)Tj-10 -1....1 TDRespconmentsmust ensibie to the)TjT*80-drh3nc0d

in Paragrapd

cpye of thtet ylu((nsAosbee(agreemens, theRespconmentf)TjT*(rerreqTirvedtn ensibie certaie othee)TjT* inormrtnc0stn aosgis th180-d

nsductA norh3uer, andcn e(coure thad)TjT*is heaesingpany reevaeno egaltet ylu((nscreeingts ivolvsingeiothee pary. Inn)TjT*adnitnc0s

nsAosbee(agreemene pr an*(Pa1TD(evTthe(nsAosbee orderalso, cnrtaise)Tj-10 -1....1 TD certaiereportsingpadg otheeensib3nc0ee)TjT* t

c-dmen onf the(agreemene It iee)TjT* not intonmedtn cnsetiutef neofficiale

agreemen,n the

nsAosbee cnsmenr