located at 74 Harbor Road, Cold Spring Harbor, operates a pumpout. The pumpout is available 24 hours a day beginning May 1 through October 31 and is self-service. No fee is charged for the use of the pumpout. This facility is located outside of the proposed NDA and is not included as one of the ten landside facility. The facility has been included in the application for information purposes.

Vessel waste generated from the pumpout facilities located at West Shore Marina, Knutson's West Marina, Huntington Yacht Club, Brittania Yacht and Seymour's are hauled by privately operated waste haulers. The Town of Huntington provides waste hauling service to the municipally owned pumpout facilities located at Cold Spring Harbor, Halesite Marina, Mill Dam Marina, Woodbine Marina, and Gold Star Mooring and Launch Service. All hauled waste from the pumpout facilities is discharged into and treated at the Town of Huntington sewage treatment plant (SPDES Permit No. NY0021342) located on Creek Road in Halesite.

According to the State's petition, the maximum daily vessel population for the waters of Greater Huntington-Northport Bay Complex is approximately 3200 vessels which are docked or moored with an additional 700 vessels accessing the greater Harbor from boat ramps. An inventory was developed including the number of recreational, commercial and estimated transient vessels that occupy or traverse the greater bay complex. This estimate is based on (1) vessels (approximately 1600 vessels) docked or moored (including transients) in the proposed NDA, (2) vessels (approximately 1600 vessels) docked or moored (including transients) in the existing Huntington/Lloyd Harbor NDA and (3) vessels (approximately 700 vessels) which use the boat ramps in the Greater Bay Complex. While approximately one-third to one-half of the vessels operating in the Greater Bay Complex are not equipped with a MSD, the ratio of boats to pumpout facilities has been based on the total number of vessels which could be expected. With ten shore-side pumpout facilities and two pumpout facilities available to boaters, the ratio of docked or moored boats (including transients) is approximately 267 vessels per pumpout. If we include the vessels (approximately 700) using the available boat ramps, the ratio increase to 325 vessels per pumpout. Standard guidelines refer to acceptable ratios failing in the range of 300 to 600 vessels per pumpout.

The EPA hereby makes a tentative affirmative determination that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the Greater Huntington-Northport Bay Complex in the county of Suffolk, New York. A final determination on this matter will be made following the 30-day period for public comment and will result in a New York State prohibition of any sewage discharges from vessels in Greater Huntington-Northport Bay Complex.

Comments and views regarding this petition and EPA's tentative determination may be filed on or before May 3, 2000. Comments or requests for information or copies of the applicant's petition should be addressed to Walter E. Andrews, U.S. Environmental Protection Agency, Region II, Water Programs Branch, 290 Broadway, 24th Floor, New York, New York, 10007–1866. Telephone: (212) 637–3880.

Dated: March 16, 2000.

Jeanne M. Fox,

Regional Administrator, Region II.

[FR Doc. 00–8146 Filed 3–31–00; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 27, 2000.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. First Merchants Corporation, Muncie, Indiana; to merge with Decatur Financial, Inc., Decatur, Indiana, and thereby indirectly acquire Decatur Bank and Trust Company, Decatur, Indiana.

B. Federal Reserve Bank of Minneapolis (JoAnne F. Lewellen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. Leackco Bank Holding Company, Inc., Wolsey, South Dakota; to merge with C&L Investment Company, Inc., Miller, South Dakota, and thereby indirectly acquire Hand County State Bank, Miller, South Dakota.

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. CBCT Bancshares, Inc., Baltimore, Maryland, to become a bank holding company by acquiring 100 percent of the voting shares of Community Bank of Central Texas, ssb, Smithville, Texas.

Board of Governors of the Federal Reserve System, March 28, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–8087 Filed 3–31–00; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 981 0395]

Abbott Laboratories, and Geneva Pharmaceuticals, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreements.

SUMMARY: The consent agreements in these two matters settle 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 agreements and the terms of the consent orders—embodied in the consent agreements—that would settle these allegations.

DATES: Comments must be received on or before April 17, 2000.

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

FOR FURTHER INFORMATION CONTACT: Richard Parker or Richard Feinstein, FTC/H–374, 600 Pennsylvania Ave., NW, Washington, DC 20580. (202) 326–2574 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 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 March 16, 2000), on the World Wide Web, at ''http://www.ftc.gov/ftc/formal.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 agreements and proposed consent orders with Geneva Pharmaceuticals, Inc. and Abbott Laboratories. The proposed consent orders settle charges that these parties unlawfully agreed that Geneva would refrain from selling its generic vision of one of Abbott's drugs, in exchange for payments from Abbott. The proposed consent orders have been placed on the public record for 30 days to receive comments by interested persons. The proposed consent orders have been entered into for settlement purposes only and do not constitute an admission by Abbott or Geneva that they violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background

Abbott Laboratories develops, manufactures, and sells a variety of health care products and services. Based in Abbott Park, Illinois, Abbott's 1998 net sales worldwide were approximately $12.5 billion. Over 20% of Abbott's net sales of pharmaceutical products in the U.S. are for a drug called Hytrin. Hytrin is used to treat two chronic conditions that affect millions of Americans, particularly senior citizens: hypertension (high blood pressure) and benign prostatic hyperplasia (enlarged prostate).

Geneva is one of the leading generic drug manufacturers in the United States. An indirect wholly-owned subsidiary of Novartis Corp., Geneva is based in Broomfield, Colorado. Geneva developed a generic version of Hytrin, and in March 1998 received approval from the U.S. Food and Drug Administration (''FDA'') to market that generic product.

A generic drug is a product that the FDA has found to be bioequivalent to a brand name drug. A company seeking FDA approval to market a new drug must file a New Drug Application (''NDA''). In order to market a generic version of a brand name drug, a company must file an Abbreviated New Drug Application (''ANDA'') and receive approval from the FDA.

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]

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 generic drugs while maintaining incentives to invest in new drug development. In particular, the Hatch-Waxman Act establishes certain rights and procedures in situations where a company 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, 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 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.

Geneva was the first company to file an ANDA for terazosin hydrochloride (''terazosin HCL''), the generic version of Hytrin. It filed applications covering a tablet form and a capsule form of its generic terazosin HCL. Geneva filed a paragraph IV certification with the FDA stating that these products did not infringe any valid patent held by Abbott covering terazosin HCL. In June 1996, Abbott sued Geneva for patent infringement by Geneva's terazosin HCL tablet product, but due to an oversight failed to mane an infringement claim against Geneva's capsule product, although both products raised the same potential infringement issues.

Abbott's lawsuit triggered a 30-month stay of final FDA approval of Geneva's terazosin HCL tablet ANDA, until December 1998. No stay applied to the FDA approval process for Geneva's terazosin HCL capsule ANDA, however, because no infringement claim was filed within the statutory time period required by the Hatch-Waxman Act. The FDA granted Geneva final approval to market generic terazosin HCL capsules on March 30, 1998.

The Challenged Agreement

The complaint challenges an agreement whereby Abbott, following the FDA approval of Geneva's generic terazosin HCL capsule product, paid

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

Geneva not to enter the market during their ongoing patent litigation over the tablet product. According to the complaint, on the day it was granted approval to market its generic terazosin HCL capsules, Geneva contacted Abbott and announced that it would launch its generic terazosin HCL capsules unless it was paid by Abbott not to enter. Two days later, on April 1, 1998, Abbott and Geneva entered into an agreement, pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) The final resolution of the patent infringement litigation involving Geneva's terazosin HCL tables product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product.

Geneva also agreed-at Abbott's insistence-not to transfer, assign, or relinquish its 180-day exclusively right. The effect of this provision was to ensure that no other company's generic terazosin HCL product could obtain FDA approval; and enter the market during the term of the agreement, because Geneva's agreement not to launch its product meant that the 180-day exclusivity period would not expire.

In exchange, Abbott agreed to pay Geneva $4.5 million per month until a district court judgment in the parties' patent infringement dispute, and then (assuming Geneva won in the district court) to pay the $4.5 million monthly payments into an escrow fund until the final resolution of the litigation, which Geneva would then receive if its district court victory was upheld.

Abbott's payment to Geneva of $4.5 million a month was well over the $1 to $1.5 million per month that, the complaint states, Abbott believed Geneva would forego by staying off the market. The complaint alleges that Abbott was willing to pay Geneva a ''premium'' to refrain from competing because of the substantial impact that launch of a generic version of Hytrin would have on Abbott's overall financial situation. Abbott forecasted that entry of generic terazosin HCL on April 1, 1998 would eliminate over $185 million in Hytrin sales in just six month. Accordingly, the complaint charges, Abbott sought to forestall Geneva—and all other potential generic competition to Hytrin-from entering the market because of the threat they represented to the high profits it was making from Hytrin.

The complaint further charges that, in accordance with the terms of the agreement, Geneva did not enter the market with its generic terazosin HCL capsules, even after the district court and the court of appeals upheld Geneva's position that Abbott's patent was invalid. In August 1999, Abbott and Geneva—aware of the Commission's investigation—terminated their agreement (which by its terms would not have ended until disposition of the litigation by the Supreme Court). Geneva finally brought its generic terazosin HCL capsule product to market on August 13, 1999.

Competitive Analysis

The complaint charges that the challenged agreement prevented competition that Abbott's Hytrin product would otherwise have faced from generic products of Geneva and other potential generic competitors. 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 directors 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. Abbott's forecasts, the complaint states, projected that generic terazosin HCL would capture roughly 70% of Hytrin sales within the first six months following its launch. The agreement, however, ensured that Geneva would not offer generic terazosin HCL in competition with Hytrin, and would not take action-such as relinquishing exclusivity rights-that would have permitted the entry of any other generic manufacturer.

These restraints on generic competition had direct and substantial effects on consumers. Without a lower-priced generic alternative, consumers, government agencies, health plans, pharmacies, hospitals, wholesalers, and others were forced to purchase Abbott's more expensive Hytrin product. Other drugs, the complaint states, are not effective substitutes for terazosin HCL because they are different in terms of chemical composition, safety, efficacy, and side effects. There is little price sensitivity between terazosin HCL and other products. Thus, the complaint alleges that the sale of terazosin HCL in the United States in the relevant market within which to assess the effects of the challenged agreement.

The challenged conduct represents an agreement not to compete between potential horizontal competitors. A firm is a potential competitor if there is evidence that entry by that firm is reasonably probable in the absence of the agreement at issue.[2] Geneva certified to the FDA that its entry with generic HCL would not infringe a valid patent, and was confident that it ultimately would prevail in its patent infringement dispute with Abbott, the complaint states. In early 1998, Geneva was making preparations to launch its generic terazosin HCL capsule product as soon as possible. After receiving FDA approval for the capsule product, Geneva threatened to launch that product unless Abbott paid it not to do so. The challenged agreement directly restrained competition between these potential competitors.

In addition, the agreement created a bottleneck that prevented any other potential competitors from entering the market, because no other ANDA filer could obtain FDA approval until Geneva's 180 day exclusivity period expired. Other companies were developing generic terazosin HCL products, and at least one other generic manufacturer had satisfied the FDA's requirements for approval by February 1999, but was barred from entering the market because Geneva's failure to launch its product meant its 180-day exclusivity right had not even begun to run.

The complaint states that the challenged agreement is not justified by any countervailing efficiency. Although the agreement between Abbott and Geneva provided substantial private benefits to both parties, the facts in this matter demonstrate that the broad restraints were not justified by any benefits to competition and consumer welfare. The Commission considered whether the agreement could be considered a procompetitive effort to effectuate a temporary settlement of a patent dispute, akin to a court-ordered preliminary injunction. However, it finds that any legitimate interest in resolving patent disputes cannot justify the harm to consumers imposed by the agreement in this case. The restraint imposed exceeds what likely would be available to the parties under a court-ordered preliminary injunction. For example, it: (1) Barred Geneva's entry beyond the pendency of the district court litigation; (2) provided large up-front payments that could be expected to create disincentives for Geneva to enter (in contrast to a court-ordered bond to cover damages actually incurred as a result of the court's injunction); (3) barred Geneva from relinquishing its

[2] Federal Trade Commission and United States Department of Justice, Antitrust Guidelines for the Licensing of Intellectual Property at § 1.1 n.6(1995)

exclusivity rights; (4) prohibited Geneva from developing or marketing non-infringing generic products. Moreover, the restraints contained in the agreement were entered into without any judicial finding that Abbott was likely to succeed on the merits of its infringement suit, without any consideration of whether Abbott would suffer irreparable injury, and without any weighing of the equities, including any consideration of the public interest.

The complaint also charges that Abbott had a monopoly in the market for terazosin HCL, and, by entering into the agreement with Geneva, Abbott sought to preserve its dominance by delaying the entry of Geneva and other generic companies into the market. As detailed above, there were no countervailing justifications for Abbott's conduct. In addition, the complaint alleges that Abbott and Geneva conspired to monopolize the market for terazosin HCL. As stated in the complaint, Abbott and Geneva acted with specific intent that Abbott monopolize the market for terazosin HCL, and entered into a conspiracy to achieve that goal. Finally, the parties' agreement otherwise amounts to an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Orders

The proposed orders are designed to remedy the unlawful conduct charged in the complaint. Although the particular agreement challenged in the complaint has been terminated, prospective relief is necessary to prevent a recurrence of similar agreements with respect to other drugs. Private agreements in which the brand name drug company (the NDA holder) pays the first generic to seek FDA approval (the first filer) not to enter the market can substantially delay generic competition and raise serious antitrust issues. Moreover, the FDA, which has expressed concern about such private agreements, has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to the brand name company from extending its monopoly increasingly exceed the potential economic gains to the generic applicant from its 180 days of market exclusivity.[3]

In essence, the proposed orders:

• Bar two particular types of agreements between brand name drug companies and potential generic competitors—restrictions on giving up Hatch-Waxman 180-day exclusivity rights and on entering the market with an non-infringing product;

• Require that agreements involving payments to the generic company to stay off the market be approved by the court when undertaken in the context of an interim settlement of patent litigation, with notice to the Commission to allow it time to present its views to the court;

• Require respondents to give the Commission written notice 30 days before entering into such agreements in other contexts; and

• Require that Geneva waive its right to 180-day marketing exclusivity for its generic terazosin HCL tablet product, so that other generic tablet producers can immediately enter the market.

Paragraph II prohibits two kinds of agreements between ''an NDA Holder'' and ''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 established under the Hatch-Waxman Act. 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 patent infringement lawsuit. The order prohibits restrictions on giving up exclusivity rights and on competing with a non-infringing product because under the circumstances of this case these restraints are not justified.

Paragraph II's focus on agreements between an NDA holder and the ANDA first filer does not mean that the Commission believes that there is no risk of competitive harm in other contexts. In particular, Abbott or Geneva's participation in an agreement in which a generic company that is not the ANDA first filer is paid by the NDA holder not to market a non-infringing product could raise substantial competitive concerns. Given the variety of circumstances in which the restraints may arise, however, and the possibility that some legitimate justifications might exist in some other contexts, the Commission believes that it is appropriate at this time to limit the flat bans in Paragraph II to agreements between NDA holders and ANDA first filers.

Paragraphs III bans private agreements involving payments to keep a generic drug off the market during patent infringement litigation brought by an NDA holder. Abbott and Geneva can enter into such arrangements only if (a) They are presented to the court and embodied in a court-ordered preliminary injunction, and (b) the following other conditions are met: (i) Along with any stipulation for preliminary injunction, they provide the court with a copy of the Commission's complaint, order, and this Analysis to Aid Public Comment in this matter, as well as the proposed agreement between the parties; (ii) at least 30 days before submitting the stipulation to the court, they provide written notice to the Commission; and (iii) they do not oppose Commission participation in the court's consideration of the request for preliminary relief.

Thus, the proposed orders bar agreements made in the context of an interim settlement of a patent infringement action, whereby the NDA holder pays the generic not to enter the market, unless the parties obtain court approval through a process that is designed to enhance the court's ability to assess the competitive implications of the agreement. This remedy, in addition to facilitating the court's access to information about the Commission's views, also makes the process public and thereby may prompt other generic drug manufacturers (or other interested parties) to alert the court to potential anticompetitive provisions that could delay their entry into the market. Furthermore, the Commission believes that the requirement that the agreement be filed on the public record with the court will deter Abbott and Geneva from entering into anticompetitive agreements.

Paragraph IV addresses certain agreements to stay off the market that are not covered by Paragraph III because they do not involve interim relief in a litigated matter. Such situations would include agreements that are part of a final settlement of the litigation, and situations in which no litigation has been brought. In these circumstances, there is no judicial role in ordering relief agreed to by the parties. The Commission is concerned about such private agreements in which the first filer is paid by the NDA holder not to enter the market, because of the substantial risk of competitive harm that they may create. Thus, the order requires that Abbott and Geneva notify the Commission 30 days before entering into an agreement in which an ANDA first filer agrees with an NDA holder to refrain from going to market. Such notice will assist the Commission in detecting anticompetitive agreements before they have caused substantial injury to consumers. Absent the order, there is no mechanism for the antitrust enforcement agencies to find out about such agreements.

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

The form of notice that Abbott and Geneva must provide to the Commission under Paragraphs III and IV of the orders is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, they are required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the orders require them to identify, among other things, all others who have filed an ANDA for a product containing the same chemical entities as the product a issue, and the court that is hearing any relevant legal proceedings involving either party. In addition, they must provide the Commission with all documents that evaluate the proposed agreement.

In addition, the proposed order against Geneva requires that it waive its 180-day marketing exclusivity period for its generic terazosin HCL tablet product. Although Geneva's exclusivity right with respect to the terazosin capsules product has expired, its exclusivity period for the tablet product still remains as a barrier to entry. This provision of the order will therefore open the market to greater generic competition in terazosin HCL products.

The proposed orders also contain 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 orders will expire in 10 years.

Opportunity for Public Comment

The proposed orders have 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 agreements and the comments received and will decide whether it should withdraw from the agreements or make the proposed orders final.

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

By direction of the Commission.

Donald S. Clark,

Secretary.

Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary

The Analysis to Aid Public Comment, published today along with proposed consent orders against Geneva Pharmaceuticals, Inc. and Abbott Laboratories, describes the conduct of those two companies in agreeing that Abbot would pay Geneva to refrain from selling a generic version of Hytrin, Abbott's branded version of terazosin hydrochloride. It also describes relevant provisions of the Drug Price competition and Patent Term Restoration Act of 1984 (''Hatch-Waxman Act''), including particularly the provision that gives the first generic company to seek FDA approval a 180-day period during which it has the exclusive right to market the generic version of a brand name drug.

Pursuant to a private agreement not reviewed by any court, Abbott paid Geneva substantial sums not to enter the market with its generic version of Hytrin, and not to transfer, assign or relinquish its 180-day exclusive marketing right to any other producer of generic products that might compete with Abbot. By not selling its generic version. Geneva prevented the start of the 180-day exclusivity period, with the result that neither Geneva nor any other company could introduce a generic version of Hytrin into the market.

These consent orders represent the first resolution of an antitrust challenge by the government to a private agreement whereby a brand name drug company paid the first generic company that sought FDA approval not to enter the market, and to retain its 180-day period of market exclusivity. Because the behavior occurred in the context of the complicated provisions of the Hatch-Waxman Act, and because this is the first government antitrust enforcement action in this area, we believe the public interest is satisfied with orders that regulate future conduct by the parties. We recognize that there may be market settings in which similar but less restrictive arrangements could be justified, and each case must be examined with respect to its particular facts.

We have today issued an administrative complaint against two other pharmaceutical companies with respect to conduct that is in some ways similar to the conduct addressed by these consent orders. We anticipate that the development of a full factual record in the administrative proceeding, as well as the public comments on these consent orders, will help to shape further the appropriate parameters of permissible conduct in this area, and guide other companies and their legal advisors.

Pharmaceutical firms should now be on notice, however, that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm. Accordingly, in the future, the Commission will consider its entire range of remedies in connection with enforcement actions against such arrangements, including possibly seeking disgorgement of illegally obtained profits.

If firms are uncertain about the limits of permissible behavior under the Hatch-Waxman Act, they may, of course, seek advisory opinions from the staff of this agency.

[FR Doc. 00–8129 Filed 3–31–00; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[File No. 971 0038]

Colegio de Cirujanos Dentistas de Puerto Rico; 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 June 2, 2000.

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

FOR FURTHER INFORMATION CONTACT: Richard Feinstein or Steven Osnowitz, FTC/S–3115, 600 Pennsylvania Ave., NW, Washington, D.C. 20580. (202) 326–2574 or 326–2746.

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