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

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 complaint. An electronic copy of the