

**FEDERAL TRADE COMMISSION****[File Nos. 001 0221, 011 0046, and 021 0181]****Bristol-Myers Squibb Company;  
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 April 7, 2003.

**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](mailto:consentagreement@ftc.gov), as prescribed below.

**FOR FURTHER INFORMATION CONTACT:**

Susan Creighton or Jeffrey Brennan, FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-2946 or 326-3688.

**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 March 7, 2003), on the World Wide Web, at <http://www.ftc.gov/os/2003/03/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 email messages directed to the following email box: [consentagreement@ftc.gov](mailto: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 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 Bristol-Myers Squibb Corporation (BMS). The proposed consent order would settle charges that BMS engaged in a series of unlawful acts to delay competition from generic versions of three of its major drug products. 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 BMS that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

The complaint charges that BMS engaged in a series of anticompetitive acts over the past decade to obstruct the entry of low-cost generic competition to three highly profitable BMS prescription drug products: BuSpar, an anti-anxiety agent; and two anti-cancer drugs, Taxol and Platinol. According to the complaint, when confronted with imminent competition to these drugs through generic entry, BMS undertook a course of conduct that includes: paying a would-be competitor \$72.5 million to abandon its challenge to a BMS patent and stay off the market until the patent expired; abusing Food and Drug Administration (FDA) regulations to block generic entry; making false statements to the FDA in connection with listing patents in the Orange Book; engaging in inequitable conduct before the U.S. Patent and Trademark Office (PTO) to obtain patents; and filing baseless patent infringement suits. As a result, the complaint alleges, consumers were forced to incur hundreds of millions of dollars in additional costs to obtain vital prescription drug products.

The proposed order is designed to remedy the pattern of unlawful conduct

charged in the complaint and prevent recurrence of such conduct, while maintaining BMS's ability to engage in legitimate activities that may promote innovation and benefit consumers.

**Background**

The proposed consent order rests in substantial part on charges that BMS abused governmental processes to delay generic competition to three of its highly successful prescription drug products and, in particular, that it misused the regulatory scheme established by Congress to expedite the approval of generic drugs.

A generic drug is a pharmaceutical product that contains the same active ingredients as its brand-name counterpart and is "bioequivalent" to the branded drug, that is, the FDA has determined there is no significant difference in the rate and extent of absorption of the two products. Generic drugs typically are sold at substantial discounts from the branded drug's price. A Congressional Budget Office report estimates that purchasers saved \$8-10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the brand-name product.<sup>1</sup>

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 for companies to invest in research and development of new drugs. A company seeking approval from the FDA to market a new drug must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. To receive FDA approval to market a generic version of a branded drug, a company files an Abbreviated New Drug Application (ANDA) demonstrating that its product is bioequivalent to its branded counterpart, but need not provide independent data on safety and efficacy.

The Hatch-Waxman Act established certain rights and procedures that apply when a company seeks approval from the FDA to market a generic product prior to the expiration of a patent or patents relating to the branded drug upon which the generic is based. An NDA applicant is required to submit to the FDA information on certain types of patents relating to the approved drug. The FDA lists the approved drug and its related patents in a publication entitled

<sup>1</sup> Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xiii, 13 (July 1998).