

credit needs of their communities, including low- and moderate-income neighborhoods, consistent with safe and sound banking practices. The Federal Reserve System uses the information in the examination process and in evaluating applications for mergers, branches, and certain other corporate activities. Financial institutions maintain and provide the information to the Federal Reserve System.

Board of Governors of the Federal Reserve System, August 14, 2008.

**Robert deV. Frieson,**

*Deputy Secretary of the Board.*

[FR Doc. E8-19189 Filed 8-19-08; 8:45 am]

BILLING CODE 6210-01-P

## FEDERAL TRADE COMMISSION

[File No. 071 0193]

### Sun Pharmaceutical Industries Ltd.; Analysis of Agreement Containing Consent Orders 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 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 September 11, 2008.

**ADDRESSES:** Interested parties are invited to submit written comments. Comments should refer to “Sun Pharmaceutical, File No. 071 0193,” to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room 135-H, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Comments containing confidential material must be filed in paper form, must be clearly labeled “Confidential,” and must comply with Commission Rule 4.9(c). 16 CFR 4.9(c) (2005).<sup>1</sup> Comments should

not include any sensitive personal information, such as an individual’s Social Security Number; date of birth; driver’s license number or other state identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records and other individually identifiable health information. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments that do not contain any nonpublic information may instead be filed in electronic form by following the instructions on the web-based form at (<http://secure.commentworks.com/ftc-SunPharmaceutical>). To ensure that the Commission considers an electronic comment, you must file it on that web-based form.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC website, to the extent practicable, at [www.ftc.gov](http://www.ftc.gov). As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC’s privacy policy, at (<http://www.ftc.gov/ftc/privacy.htm>).

**FOR FURTHER INFORMATION CONTACT:** David L. Inglefield, Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, (202) 326-2637.

**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 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 August 13, 2008), on the World Wide Web, at (<http://www.ftc.gov/os/2008/08/index.htm>). A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW, Washington, D.C. 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. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before the date specified in the **DATES** section.

### Analysis of Agreement Containing Consent Order to Aid Public Comment

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Sun Pharmaceutical Industries Ltd. (“Sun”) which is designed to remedy the anticompetitive effects of the acquisition of Taro Pharmaceutical Industries Ltd. (“Taro”) by Sun. Under the terms of the proposed Consent Agreement, Sun is required to divest all of Sun’s rights and assets necessary to manufacture and market: (1) generic immediate-release carbamazepine tablets; (2) generic chewable carbamazepine tablets; and (3) generic extended-release carbamazepine tablets to Torrent Pharmaceuticals Ltd. (“Torrent”).

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to an Agreement of Merger executed on May 18, 2007, Sun proposed to acquire all of the issued and outstanding shares of Taro in a transaction then valued at approximately \$454 million. In the event that agreement has been properly terminated, as Taro claims, Sun intends to acquire controlling interest in Taro via an Option Agreement executed at the time of the merger agreement and/or via a tender offer. The Commission’s Complaint alleges that the proposed

<sup>1</sup> The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the

Commission’s General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the U.S. markets for the manufacture and sale of generic immediate-release carbamazepine tablets and chewable carbamazepine tablets, and in the research, development, manufacture and sale of extended-release carbamazepine tablets (collectively, the "Products"). The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

Sun, headquartered in Mumbai, India, is a leading developer, manufacturer, marketer, and distributor of niche pharmaceuticals in its home country and active pharmaceutical ingredients (APIs) and generic drugs worldwide. Sun is intent on growing its U.S. generic drugs business and sells generic pharmaceuticals in the United States through wholly-owned Caraco Pharmaceutical Laboratories Ltd. Taro, headquartered in Israel, also develops and manufactures generic pharmaceutical products, primarily for sale in the United States.

### **The Products and Structure of the Markets**

The proposed acquisition of Taro by Sun would increase Sun's worldwide position in generic pharmaceuticals and augment Sun's pipeline of future generic products. Sun and Taro overlap in a number of generic pharmaceutical markets, and if consummated, the transaction likely would lead to anticompetitive effects in the markets for three different forms of carbamazepine. Carbamazepine is an anticonvulsant that is used primarily as an anti-epileptic drug. It is taken daily, either alone or in combination with other drugs, to prevent and control seizures.

The transaction would reduce the number of competing generic suppliers in the overlap markets. The number of generic suppliers has a direct and substantial effect on generic pricing as each additional generic supplier can have a competitive impact on the market. Because there are at least two generic equivalents for each of the products at issue, the branded versions no longer significantly constrain the price of the generic drugs.

Generic immediate-release carbamazepine tablets are AB-rated generic versions of Novartis's Tegretol®. In this market, Taro is the leading supplier with half the market. Teva

Pharmaceutical Industries Ltd. ("Teva") follows with more than a quarter of the market, and Sun's Caraco is the third-leading supplier with a share of about 18 percent. The only other supplier currently in the market is Apotex.

Generic chewable carbamazepine tablets are a chewable form of the anticonvulsant that carry the same label and indications as the immediate-release tablets. They are prescribed in the same way as the immediate-release products, but come in a more convenient dosing form, which makes them better-suited for pediatric, geriatric, and other patients who may have difficulty swallowing pills. With a market share of 65 percent, Teva is the leading seller of the generic chewable carbamazepine tablets in 2007, followed by Taro with a share of about 31 percent and Sun, with a share of only 4 percent in 2007. Cadista, the only other approved supplier of generic chewable carbamazepine tablets, is not supplying the product currently.

Sun and Taro are the only companies that have applied for Food and Drug Administration ("FDA") approval of generic versions of Novartis's Tegretol®-XR extended-release carbamazepine tablets. This extended-release formulation of the drug is indicated for the same uses as the immediate release products but offers the added convenience of a less frequent dosing regimen.

### **Entry**

Entry into the markets for the manufacture and sale of any of these three carbamazepine products would not be timely, likely or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and FDA drug approval requirements takes at least two years. Entry would not be likely because the relevant markets are relatively small and in decline, so the limited sales opportunities available to a new entrant are likely insufficient to warrant the time and investment necessary to enter.

### **Competitive Effects**

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic immediate-release carbamazepine tablets, generic chewable carbamazepine tablets, and generic extended-release carbamazepine tablets. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given

market. Both empirical research and the Commission's many investigations into generic drug competition confirm that finding. Here, the evidence shows that, given the small number of suppliers or prospective suppliers in the relevant markets, the prices of the generic pharmaceutical products at issue decrease with the entry of each additional competitor.

Among currently-marketed products, the acquisition would reduce the number of firms producing generic chewable carbamazepine tablets from three to two, with Teva being the only remaining competitor (at least until Cadista is able to re-enter the market). Similarly, the proposed transaction would reduce from four to three the number of firms remaining in the immediate-release carbamazepine tablet market, leaving Teva as the only other significant player. In the market for generic versions of extended-release carbamazepine tablets, the merging parties are the only two firms in the process of entering, so the proposed transaction likely would eliminate the generic competition that would otherwise exist in that market when the products are introduced.

As the market share information suggests, the proposed transaction would eliminate one of a small number of suppliers in the markets for two currently-marketed generic carbamazepine products, with the likely result that prices would increase above current levels. For extended-release generic carbamazepine, the consolidation would result in a merger to monopoly, with the likely result that prices would be higher than they would be without the transaction and both companies had entered independently.

The competitive concerns can be characterized as both unilateral and coordinated in nature. The homogenous nature of the products involved, the minimal incentives to deviate, and the relatively predictable prospects of gaining new business all indicate that the firms in the market will find it profitable to coordinate their pricing. The impact that a reduction in the number of firms would have on pricing can also be explained in terms of unilateral effects, as the likelihood that the merging parties would be the first and second choices in a significant number of bidding situations is enhanced where the number of firms participating in the market decreases substantially.

### **The Consent Agreement**

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in

the relevant product markets. Pursuant to the Consent Agreement, Sun is required to divest all of its rights and assets related to the Products to a Commission-approved acquirer no later than the earlier of ten (10) days after the acquisition occurs or ten (10) days after the Commission's Order becomes final. Specifically, the proposed Consent Agreement requires that Sun divest its assets in the Products to Torrent Pharmaceutical Limited ("Torrent").

The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems.

Torrent, a growing generic manufacturer, headquartered in India, is particularly well-positioned to manufacture and market its acquired products and compete effectively in those markets. Currently, Torrent sells generic pharmaceuticals in the United States but none of the relevant products, and therefore its acquisition of the relevant products would not raise independent competitive concerns. Torrent has numerous Abbreviated New Drug Applications (ANDAs) pending approval at the FDA, and has the resources, capabilities, reputation, and experience in marketing generic products, as well as a central focus on rapidly growing its U.S. generic drugs business, necessary to expeditiously replicate the competition that would be lost with the proposed acquisition.

If the Commission determines that Torrent is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Torrent is not acceptable, Sun must unwind the sale and divest the assets within six (6) months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six (6) months, the Commission may appoint a trustee to divest the Products.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Sun to provide transitional services to enable the Commission-approved acquirer to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Sun.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is

not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

**Donald S. Clark**

*Secretary*

[FR Doc. E8-19213 Filed 8-19-08; 8:45 am]

**BILLING CODE 6750-01-S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Mine Safety and Health Research Advisory Committee, National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

*Time and Date:* 8 a.m.—5:30 p.m., September 25, 2008.

*Place:* Hilton Garden Inn, 7830 S. Las Vegas Boulevard, Las Vegas, Nevada 89123, telephone (702) 453-7830, fax (702) 453-7850.

*Status:* Open to public, limited only by the space available. The meeting room accommodates approximately 50 people.

*Purpose:* This committee is charged with providing advice to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NIOSH, on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), Section 102(b)(2).

*Matters To Be Discussed:* The meeting will focus on diesel monitoring and control research, communications and tracking developments, training research, chemical hazards in mining, and dust monitoring and control research. The agenda will also include an update from the Associate Director for Mining, NIOSH.

Agenda items are subject to change as priorities dictate.

#### **CONTACT PERSON FOR MORE INFORMATION:**

Jeffery L. Kohler, PhD, Executive Secretary, Mine Safety and Health Research Advisory Committee, NIOSH, CDC, 626 Cochran Mill Road, Pittsburgh, Pennsylvania 15236, telephone: (412) 386-5301, Fax (412) 386-5300.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of

meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 13, 2008.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E8-19240 Filed 8-19-08; 8:45 am]

**BILLING CODE 4163-18-P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Proposed Project:*

*Title:* Early Head Start Family and Child Experiences Survey (Baby FACES).

#### OMB No. New Collection

*Description:* The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is conducting a descriptive study of Early Head Start Programs (Early Head Start Family and Child Experiences Survey, or Baby FACES). Baby FACES is a longitudinal study of a nationally representative sample of programs and children in two cohorts (perinatal and age 1) that will collect information about programs, services, families, and children. Data for Baby FACES will be annually collected through interviews with parents, teachers, home visitors, and program directors/managers, as well as direct child assessments, videotaped parent child interactions, and observations of the home environment when children are two and three years old. Data collection will also include quality observations of child care center classrooms and home visits conducted by program staff.

Data will be collected on a sample of approximately 2,000 children and families selected at random from 90 Early Head Start programs. Over the life of the project, Baby FACES will involve four waves of data collection, ending when the second cohort of children (perinatal cohort) reaches 36 months of age. This information collection request covers the first three years of data collection. All waves of data collection will acquire program level information through an hour-long program director interview. Additionally, staff from all programs will complete a simple service