FEDERAL TRADE COMMISSION

[File No. 061 0220, Docket No. C–4180]

Johnson & Johnson and Pfizer Inc.; 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 January 11, 2007.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''Johnson & Johnson and Pfizer, File No. 061 0220,'' 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, NW., Washington, DC 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).[1] 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 as part of or as an attachment to e-mail messages directed to the following e-mail box: *consentagreement@ftc.gov*.

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 Web site, to the extent practicable, at *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 Web site. 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: Michael R. Moiseyev, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–3106.

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 December 12, 2006), on the World Wide Web, at *http://www.ftc.gov/os/2006/12/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. 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.

I. 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 Johnson & Johnson (''J&J'') and Pfizer Inc. (''Pfizer''), which is designed to remedy the anticompetitive effects that would otherwise result from J&J's proposed acquisition of Pfizer Consumer Healthcare. Under the terms of the proposed Consent Agreement, the parties will be required to divest: (1) Pfizer's Zantac® H–2 blocker business; (2) Pfizer's Cortizone® hydrocortisone anti-itch business; (3) Pfizer's Unisom® nighttime sleep-aid business; and (4) J&J's Balmex® diaper rash treatment business.

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 will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (''Order'').

Pursuant to a Stock and Asset Purchase Agreement dated June 25, 2006, J&J proposes to acquire certain voting securities and assets comprising Pfizer's Consumer Healthcare business in a transaction valued at approximately $16.6 billion (''Proposed Acquisition''). The Commission's complaint alleges that the Proposed 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 United States markets for the research, development, manufacture, distribution, and sale of the following over-the-counter (''OTC'') medications: (1) H–2 blockers, (2) hydrocortisone anti-itch products, (3) nighttime sleep-aids, and (4) diaper rash treatments (the ''Products'').

II. The Parties

J&J is one of the largest and most diversified suppliers of branded consumer health care products in the world, as well as a manufacturer and supplier of pharmaceuticals, medical devices, and diagnostic products. In 2005, J&J had worldwide net sales of $50.5 billion. The more than 230 J&J operating companies employ approximately 116,000 individuals in 57 countries and sell products throughout the world. In the consumer products segment, J&J manufactures and markets a broad range of OTC medications, women's health products, nutritional products, oral care products, and products used for baby and skin care. With its Pepcid® line of products, J&J is the leading supplier of OTC H–2 blocker acid relief products in the United States. J&J is also a leading supplier of OTC hydrocortisone-based anti-itch medications under its Cortaid® and Aveeno® brands and of OTC nighttime sleep-aids under its Simply Sleep® brand. J&J is also a leading supplier of products for treating diaper

[1] 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).

rash under its Balmex®, Aveeno®, and Johnson's® No More Rash® brands.

Pfizer is one of the largest pharmaceutical companies in the world. Pfizer researches, develops, manufactures, and markets leading prescription medicines for humans and animals, as well as consumer healthcare products. In 2005, Pfizer had worldwide net sales of $51.3 billion. Pfizer Consumer Healthcare, which J&J proposes to acquire, is a global business that researches, develops, manufactures, and markets many well-known brands of OTC medications and oral care products to consumers throughout the world. In 2005, Pfizer Consumer Healthcare generated net sales of $3.9 billion. Like J&J, Pfizer is one of the leading suppliers of OTC H–2 blocker acid relief products in the United States with its Zantac® product line. Pfizer is also the leading supplier in the United States of OTC hydrocortisone anti-itch medications under its Cortizone® brand, OTC nighttime sleep-aids under its Unisom® brand, and diaper rash products under its Desitin® brand.

III. OTC H–2 Blockers

One of the relevant markets in which to assess the competitive effects of the Proposed Acquisition is the United States market for OTC H–2 blockers. H_2-receptor antagonists, more commonly known as ''H–2 blockers,'' are a class of drugs for the prevention and relief of heartburn associated with acid indigestion. Originally a prescription medicine, H–2 blocker products were later approved by the FDA for sale without a prescription. H–2 blockers work by blocking histamine from stimulating the gastric parietal cells, thereby suppressing secretion of stomach acid. Although there are other OTC acid relief medications, including antacids and proton pump inhibitors (''PPIs''), H–2 blockers are sufficiently different from these other products that they are not close economic substitutes. Currently, Prilosec OTC® is the only PPI available without a prescription. OTC PPIs are not a close substitute for OTC H–2 blockers because they are indicated for the relief of chronic heartburn and not for immediate relief of occasional heartburn or indigestion. Antacid tablets and liquids are not a close substitute for OTC H–2 blockers because they are less efficacious and do not provide as long relief as H–2 blockers.

The United States market for OTC H–2 blockers is highly concentrated. Today, this approximately $360 million market comprises four branded products—J&J's Pepcid®, Pfizer's Zantac®, GlaxoSmithKline's Tagamet®, and Reliant Pharmaceutical's Axid AR®—and private label versions of some Pepcid®, Zantac®, and Tagamet® products. J&J and Pfizer are the two largest suppliers in this market.

The Proposed Acquisition would significantly increase market concentration and eliminate substantial competition between the two leading suppliers of OTC H–2 blockers in the United States. Branded manufacturers of these products spend significant sums of money annually to create and maintain distinct brand equities. As a result of the acquisition, J&J would account for over 70% of the sales of OTC H–2 blocker in the United States. Here the evidence confirmed that Pepcid® and Zantac® are close substitutes. Consumers have benefitted from the competition between Pfizer and J&J on pricing, discounts, promotional trade spending, and product innovation. Thus, unremedied, the Proposed Acquisition likely would cause significant anticompetitive harm by enabling J&J to profit by unilaterally raising the prices of one or both products above pre-merger levels, as well as reducing its incentives to innovate and develop new products.

IV. OTC Hydrocortisone Anti-Itch Products

A second relevant product market in which to assess the competitive effects of the Proposed Acquisition is the United States market for OTC hydrocortisone anti-itch products. Hydrocortisone is a corticosteroid that reduces or inhibits the actions of chemicals in the body that cause inflammation, redness and swelling. OTC products containing up to 1.0 percent hydrocortisone are approved by the FDA for topical application to treat minor skin irritations, itching, and rashes due to various conditions, including dermatitis, eczema, and psoriasis. Although OTC topical anesthetic and antihistamine products are available to treat minor skin irritations, itching and rashes, these products are not close economic substitutes for hydrocortisone anti-itch products because they work differently than hydrocortisone products. While these products may relieve symptoms of pain or itching, unlike hydrocortisone, they do nothing to cure or prevent the actual underlying skin conditions such as eczema or psoriasis.

The United States market for OTC hydrocortisone anti-itch products is highly concentrated. There are only two significant branded competitors in this market: (1) Pfizer, with its Cortizone® products and (2) J&J, with its Cortaid® products. In addition, private label hydrocortisone anti-itch products account for a significant share of the market. Pfizer's Cortizone® is the market leader among branded products, while J&J's Cortaid® is the second leading branded product line. In 2005, sales of OTC hydrocortisone anti-itch products in the United States totaled approximately $120 million.

The Proposed Acquisition would significantly increase market concentration and eliminate substantial competition between the two leading suppliers of OTC hydrocortisone anti-itch products in the United States. As a result of the acquisition, J&J would account for over 55% of the sales of OTC hydrocortisone anti-itch products in the United States. Evidence indicates that the parties' products compete on many levels, including pricing, shelf-space, and advertising. By eliminating competition between the two leading branded suppliers, the Proposed Acquisition would likely result in higher prices, less promotional spending, and reduced product innovation. Although private label OTC hydrocortisone anti-itch products account for a significant share of the market, private label products are less close substitutes for a significant share of customers, and it is unlikely that private label products would be able to reposition themselves to replace the competition between J&J and Pfizer, the two largest branded competitors in this market, that would be lost through the Proposed Acquisition. Thus, unremedied, the Proposed Acquisition likely would cause significant anticompetitive harm by enabling J&J to profit by unilaterally raising the prices of one or both products above pre-merger levels, as well as reducing its incentives to innovate and develop new products.

V. OTC Nighttime Sleep-Aids

A third relevant product market in which to assess the competitive effects of the Proposed Acquisition is the United States market for OTC nighttime sleep-aids. OTC nighttime sleep-aids are non-prescription drugs that are indicated solely for the relief of occasional sleeplessness by individuals who have difficulty falling asleep. The active ingredient in the best-selling sleep-aids is a sedating antihistamine, such as diphenhydramine hydrochloride or doxylamine succinate. Prescription sleep-aids, such as zolpidem (Ambien®), zaleplon (Sonata®) or eszopiclone (Lunesta®), are not close economic substitutes for OTC nighttime sleep-aids. Consumers of OTC nighttime sleep-aids likely would not switch to prescription sleep-aids in response to a 5 to 10 percent increase

in the price of OTC nighttime sleep-aids because of the higher prices of prescription sleep-aids (particularly for those without insurance coverage) and the inconvenience and cost of a doctor's visit (including delays for consumers who have exhausted their prescriptions).

The United States market for OTC nighttime sleep-aids is highly concentrated. J&J and Pfizer are the two largest suppliers of branded OTC nighttime sleep-aids in the United States. Pfizer is the market leader with its Unisom® products, while J&J is the second leading supplier with its Simply Sleep® products. In 2005, sales of OTC nighttime sleep-aids in the United States totaled approximately $100 million.

The Proposed Acquisition would significantly increase market concentration and eliminate substantial competition between the two leading suppliers of OTC nighttime sleep-aids in the United States. As a result of the acquisition, J&J would account for over 45% of the sales of OTC nighttime sleep-aids in the United States. In addition, the evidence confirmed that Unisom® and Simply Sleep® are close substitutes and have similar efficacy, brand equity, and brand positioning. Consumers have benefitted from the competition between Pfizer and J&J on pricing, discounts, promotional trade spending, and product innovation. Although private label OTC nighttime sleep-aids account for a significant share of the market, private label products are less close substitutes for a significant share of customers, and it is unlikely that private label products would reposition themselves to replace the competition between J&J and Pfizer, the two largest branded competitors in this market, that would be lost through the Proposed Acquisition. Thus, unremedied, the Proposed Acquisition likely would cause significant anticompetitive harm by enabling J&J to profit by unilaterally raising the prices of one or both products above pre-merger levels, as well as reducing its incentives to innovate and develop new products.

VI. OTC Diaper Rash Treatments

A fourth relevant product market in which to assess the competitive effects of the Proposed Acquisition is the United States market for OTC diaper rash treatment products. Consumers use diaper rash creams or ointments to treat and prevent diaper rash and to protect sore or chafed skin from moisture or irritation. Most diaper rash products fall into one of two categories: (1) Creams or pastes containing the active ingredient zinc oxide and (2) ointments containing the active ingredient petrolatum. There are no close substitutes for OTC diaper rash creams or ointments.

The United States market for OTC diaper rash treatments is highly concentrated. Today, three large, established brands—Pfizer's Desitin®, Schering-Plough's A&D®, and J&J's Balmex®—account for over 70% of sales in this approximately $84 million market. The rest of the market is composed of several small, niche brands. Private label products account for a negligible share of the market. Pfizer is the largest supplier of OTC diaper rash treatment products with its Desitin® line of products, while J&J is the third largest supplier with its Balmex®, Aveeno®, and Johnson's® No More Rash® brands. Neither the Aveeno® nor the Johnson's® No More Rash® brands, however, account for a significant share of sales in this market.

The Proposed Acquisition would significantly increase market concentration and eliminate substantial competition between the two leading suppliers of OTC diaper rash treatment products in the United States. As a result of the acquisition, J&J would account for nearly 50% of the sales of OTC diaper rash treatment products in the United States. Although there are additional suppliers of branded OTC diaper rash treatment products in this market, the evidence confirmed that Desitin® and Balmex® are perceived to be close substitutes by consumers, and evidence suggests that they are similar in formulation, texture, and appearance. Consumers have benefitted from the competition between Pfizer and J&J on pricing, discounts, promotional trade spending, and product innovation. Thus, unremedied, the Proposed Acquisition likely would cause significant anticompetitive harm by enabling J&J to profit by unilaterally raising the prices of one or both products above pre-merger levels, as well as reducing its incentives to innovate and develop new products.

VII. Entry

Entry into the markets for the research, development, manufacture, and sale of the Products is unlikely to deter or counteract the anticompetitive effects of the Proposed Acquisition. Each of the relevant markets is relatively mature and dominated by a few well-established brand names. In such a market environment, a new entrant faces a difficult task of convincing retailers to carry its product, especially if the new product does not have a competitive advantage based on differentiated claims or efficacy. Developing and obtaining Food and Drug Administration approval for the manufacture and sale of a novel, differentiated medication takes at least two (2) years. Once product development is complete, a new entrant must invest extremely high sunk costs on marketing, advertising, and promotional allowances to create and maintain consumer awareness and acceptance of the new product. Given the sales opportunities available in the markets for the Products, coupled with the significant investment necessary to market and sell the Products, it is unlikely that a new competitor will enter any of the markets for the Products.

VIII. The Consent Agreement

The Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant markets discussed above. The Consent Agreement preserves competition in these markets by requiring the divestiture of: (1) All assets related to the Zantac® H–2 blockers to Boehringer Ingelheim Pharmaceuticals, Inc. (''Boehringer Ingelheim Pharmaceuticals''); and (2) all assets relating to Cortizone® hydrocortisone anti-itch products, all assets relating to Unisom® sleep-aids, and all assets relating to Balmex® diaper rash treatment products to Chattem, Inc. (''Chattem'') (the ''Divested Assets''). These divestitures must take place within fifteen days after the closing of the Proposed Acquisition or January 2, 2007, whichever is later.

The Commission is satisfied that Boehringer Ingelheim Pharmaceuticals is a well-qualified acquirer of the Zantac business. Boehringer Ingelheim Pharmaceuticals engages in the research, development, sale and marketing of branded pharmaceuticals and OTC drugs, including well known brands such as Dulcolax®, Spiriva®, Atrovent®, Combivent®, Flomax® and Mirapex®. Boehringer Ingelheim Pharmaceuticals is part of the Boehringer Ingelheim Group, which is a leading worldwide manufacturer of pharmaceuticals for humans and animals and the eighth largest manufacturer and marketer of OTC health care products worldwide. Boehringer Ingelheim Pharmaceutical's Consumer Health Care business has an existing sales and distribution network that sells products through the same channels as Zantac® is currently sold, and has a strong record of integrating product acquisitions successfully.

The proposed Consent Agreement contains several provisions designed to ensure the successful divestiture of the

Zantac® business to Boehringer Ingelheim Pharmaceuticals by requiring that: (1) J&J divest to Boehringer Ingelheim Pharmaceuticals all assets relating to Pfizer's Zantac® line of products, including all research and development, intellectual property, and customer and supply contracts; (2) J&J and Pfizer take steps to ensure that confidential business information relating to Zantac® will not be obtained or used by J&J; (3) Boehringer Ingelheim Pharmaceuticals have the opportunity to enter into employment contracts with certain key individuals who have experience relating to Zantac®; and (4) certain management employees of Pfizer who were substantially involved in the research, development or marketing of Zantac® be precluded from working on competitive H–2 blocker products at J&J for a period of two years.[2]

The Commission is also satisfied that Chattem is a well-qualified acquirer of the Cortisone®, Unisom®, and Balmex® businesses. Chattem is a leading manufacturer and marketer of a broad portfolio of branded OTC healthcare products, toiletries, and dietary supplements, including brands such as Icy Hot®, Gold Bond®, Selsun blue®, Garlique®, Pamprin®, and BullFrog®. Chattem's products are among the market leaders in their respective categories across food, drug and mass merchandisers. Chattem has an experienced sales force with existing relationships with major retailers and has a strong record of integrating prior product acquisitions successfully.

The proposed Consent Agreement contains several provisions designed to ensure the successful divestiture of the Cortisone®, Unisom®, and Balmex® businesses to Chattem by requiring that: (1) J&J divest to Chattem all assets relating to the Cortisone®, Unisom®, and Balmex® line of products, including all research and development, intellectual property, and customer and supply contracts; (2) J&J and Pfizer take steps to ensure that confidential business information relating to Cortisone®, Unisom®, and Balmex® will not be obtained or used by J&J; and (3) Chattem have the opportunity to enter into employment contracts with certain key individuals who have experience relating to Cortisone®, Unisom®, and Balmex®.

The Order to Maintain Assets that is included in the proposed Consent Agreement requires that J&J and Pfizer maintain the viability of the Divested Assets for the brief transition period between the time the Commission approves the proposed Order and when the divestitures take place, which will not be later than January 2, 2007. Even though such a period is relatively short, maintenance of current supply, advertising and promotional levels and activities at all times prior to divestiture is of paramount importance. The proposed Consent Agreement incorporates this plan in the Order to Maintain Assets, detailing requirements for the assets that must be held separate, services that may be shared with the ongoing business, and the employee positions that are necessary for the held separate business.

The Commission has appointed David Painter of LECG as Interim Monitor to oversee the transfer of assets, the establishment of appropriate firewalls to prevent the transfer or use of confidential business information and to ensure that J&J and Pfizer comply with all other provisions of the Order. To ensure that the Commission remains informed about the status of the Divested Assets and their transfer, the proposed Consent Agreement requires J&J and Pfizer to file reports with the Commission periodically until the divestitures are accomplished.

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 Decision and Order or the Order to Maintain Assets, or to modify their terms in any way.

By direction of the Commission with Commissioners Harbour, Kovacic and Rosch recused.

Donald S. Clark,

Secretary.

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[2] This firewall will prevent J&J from taking competitive advantage of know-how, product development, marketing, and sales plans relating to Zantac®.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–07–07AA]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Pilot Project for a National Monitoring System for Major Adverse Effects of Medication Use During Pregnancy and Lactation—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This data collection is based on the following components of the Public Health Service Act: (1) Act 42 U.S.C. 241, Section 301, which authorizes ''research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.'' (2) 42 U.S.C. 247b–4, Section 317 C, which authorizes the activities of the National Center on Birth Defects and Developmental Disabilities. This section was created by Public Law 106–310, also known as ''the Children's Health Act of 2000.'' This portion of the code has also been amended by Public Law 108–154, which is also known as the ''Birth Defects and Developmental Disabilities Prevention Act of 2003''.

The use of a number of medications during pregnancy is known to be associated with serious adverse effects in children. However, because pregnant and lactating women are traditionally excluded from clinical trials, and because premarketing animal studies do not necessarily predict the experience of humans, little information is available about the safety of most prescription