

it. Inverness' acquisition of the ACON assets further entrenched Inverness' monopoly power in consumer pregnancy tests by preventing future competition from competing water-soluble dye consumer pregnancy tests.

#### IV. The Proposed Order

The proposed order will remedy the Commission's competitive concerns about Inverness' conduct in maintaining its consumer pregnancy test product monopoly power.

First, the proposed order contains provisions to prevent Inverness from interfering with the digital consumer pregnancy test product joint venture between ACON and Church & Dwight, and to enable ACON and Church & Dwight to maintain their competitive viability after the joint venture ends. These provisions include a requirement that Inverness disclaim any ownership rights on intellectual property developed during the joint venture. The proposed order further requires that Inverness will not interfere with ACON's transfer or licensing of digital consumer pregnancy test technology to Church & Dwight, and that Inverness not interfere with ACON's ability to manufacture digital consumer pregnancy tests for Church & Dwight during their collaboration.

Second, to prevent Inverness from harming emerging competition from water-soluble dye consumer pregnancy test products, the proposed order requires Inverness to divest, to Aemoh Products, LLC, a fully-paid perpetual exclusive sublicense to Inverness' water-soluble dye intellectual property. The proposed order seeks to ensure that water-soluble dye products can be developed without risk of infringing Inverness' intellectual property, by requiring Inverness to covenant not to assert intellectual property infringement claims against certain lateral flow products that use Inverness' water-soluble dye technology. These provisions, among others, will give Aemoh—a start-up run by a successful and experienced health products entrepreneur—the ability to complete the commercialization of water-soluble dye based consumer pregnancy tests.

#### V. Opportunity for Public Comment

The proposed consent order has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed consent order and the comments received and will decide whether it should withdraw

from the agreement or make the proposed consent order final.

By accepting the proposed Consent Agreement subject to final approval, the Commission anticipates that the competitive problems alleged in the complaint will be resolved. The purpose of this analysis is to invite public comment on the proposed Consent Agreement, in order to aid the Commission in its determination of whether to make the proposed order final. This analysis is not intended to constitute an official interpretation of the proposed order nor is it intended to modify the terms of the proposed order in any way.

By direction of the Commission, Commissioner Harbour recused.

**Richard C. Donohue,**

*Acting Secretary.*

[FR Doc. E8-31366 Filed 1-2-09; 8:45 am]

**BILLING CODE 6750-01-S**

### FEDERAL TRADE COMMISSION

[File No. 081 0240]

#### King Pharmaceuticals, Inc. and Alpharma Inc.; Agreement Containing Consent Order 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 27, 2009.

**ADDRESSES:** Interested parties are invited to submit written comments. Comments should refer to “King AlphaPharma, File No. 081 0240,” 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> 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-KingAlphaPharma>). 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.shtm>).

**FOR FURTHER INFORMATION CONTACT:** James Southworth, FTC Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, (202) 326-2822.

**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

<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).

Home Page (for December 29, 2008), on the World Wide Web, at (<http://www.ftc.gov/os/2008/12/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

### I. Introduction

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from King Pharmaceuticals, Inc. (“King”) and Alpharma Inc. (“Alpharma”), which is designed to remedy the anticompetitive effects of King’s acquisition of Alpharma. Under the terms of the Consent Agreement, the companies would be required to divest to Actavis all rights to Kadian, Alpharma’s branded long-acting morphine sulfate opioid analgesic product. Kadian’s patent runs until April of 2010. The divestiture gives Actavis all rights to Kadian, restoring the competition between Kadian and King’s Avinza that would be lost with the acquisition.

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 a merger agreement executed on November 23, 2008, King intends to acquire all the outstanding shares of Alpharma for approximately \$1.6 billion. Both parties sell branded pharmaceuticals in the United States. 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 FTC Act, as amended, 15 U.S.C. § 45. The proposed Consent Agreement remedies the alleged violations by maintaining existing competition between branded Kadian and Avinza, and permitting an

authorized generic version of branded Kadian to be launched prior to when the patent expires.

### II. The Competitive Effects of the Proposed Acquisition

The proposed acquisition would cause significant anticompetitive harm by eliminating actual, direct and substantial competition between King and Alpharma in the market for oral long acting opioid analgesics (“oral LAOs”). The merging firms today offer the only two competitively significant branded morphine sulfate oral LAOs, and the evidence shows that they are particularly close competitors within the larger oral LAO market. The loss of head-to-head competition between King’s Avinza and Alpharma’s Kadian would result in higher prices for branded ER morphine sulfate.

While King and Alpharma oral LAO products compete most directly with each other, they also compete, to a lesser extent, with other oral LAOs. Oral LAOs have become the standard of care for the management of moderate-to-severe chronic pain because of their effectiveness, ease of titration and favorable risk-to-benefit ratio. Other oral LAOs are based on distinct chemical compounds, but all of these products have the same mechanisms of action, similar indications, similar dosage forms and similar dosage frequency. The most significant of the other oral LAOs is Purdue Pharma L.P.’s OxyContin, which is four times larger than Avinza and Kadian, combined. A fourth product, Endo Pharmaceutical’s Opana ER, also competes in the market.

As with most pharmaceutical products, entry into the manufacture and sale of oral LAOs, is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration (“FDA”) approval for the manufacture and sale of oral LAOs takes at least two years due to substantial regulatory, technological and intellectual property barriers. As a result, new entry is unlikely to ameliorate the anticompetitive effects of the acquisition.

### III. The Consent Agreement

The order would remedy the competitive concerns raised by the proposed acquisition by requiring King to divest Kadian to Actavis no later than ten days after its acquisition of Alpharma is consummated. Headquartered in Iceland, Actavis is one of the world’s largest generic pharmaceutical companies. Currently, Actavis manufactures Kadian for Alpharma at its plant located in Elizabeth, New Jersey. With the

divestiture, Actavis will continue to sell Kadian in competition with Avinza and other oral LAOs, and be able to introduce an “authorized” generic version of Kadian earlier than would have been otherwise possible, as Kadian’s patent expires in April of 2010. An “authorized” generic is a pharmaceutical product that was originally marketed and sold by a brand company but is relabeled and marketed under a generic product name. As the current manufacturer of Kadian for Alpharma, Actavis has the incentive and ability to launch the first generic Kadian product prior to patent expiry.

The assets to be divested include all intellectual property and regulatory approvals, inventory, books and records, marketing materials, and assumed contracts necessary for Actavis to sell Kadian as either a branded or generic product. Because Actavis already manufactures Kadian, no divestiture of fixed assets, interim supply agreement, provision of technical assistance is required, or asset maintenance order are required.<sup>2</sup> The proposed order also contains provisions designed to restrict King’s use of confidential business information relating to Kadian.

The FTC’s prior orders involving the divestiture of branded pharmaceutical products have required that any buyer of branded products have the requisite brand marketing experience to replace the competition that would have been eliminated through the transactions. However, the Commission has determined that the divestiture of Kadian to the generic drug manufacturer Actavis is an appropriate remedy in this case because (1) with only a little over a year left to Kadian’s patent life, further innovation of the Kadian product is unlikely, and (2) the proposed remedy not only prevents the loss of price competition between Avinza and Kadian which was the competitive concern identified in our investigation, but also makes possible early introduction of a generic product—with lower pricing for consumers—before the patent expires.

In the event that the Commission determines that Actavis is not an acceptable acquirer, the proposed order requires the parties to unwind the sale and then divest Kadian within six months of the date the order becomes final to another Commission-approved acquirer. The proposed order also provides that, in the event that the Commission determines that the manner of the divestiture is not acceptable, that the Commission may appoint a

<sup>2</sup> The proposed order requires the respondents to maintain the assets pending divestiture.

divestiture trustee to effectuate such modifications as are necessary to satisfy the requirements of the order.

Additionally, the proposed order allows the Commission to appoint an Interim Monitor to ensure the respondents' compliance with the terms of the order.

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 Consent Agreement or to modify its terms in any way.

By direction of the Commission, Commissioner Harbour recused.

**Donald S. Clark,**

Secretary.

[FR Doc. E8-31386 Filed 1-2-09; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0990—New]

**Agency Information Collection Request. 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request

for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60-days.

*Proposed Project:* Evaluation of the Parents Speak Up National Campaign (PSUNC): National Media Tracking Surveys. OMB No. 0990-NEW-Office of Public Health and Science, Office of Population Affairs, Office of Adolescent Pregnancy Programs

*Abstract:* The OS proposes to conduct a national media tracking

survey as part of the Parents Speak Up National Campaign. The U.S. Department of Health and Human Services (USDHHS) launched the Parents Speak Up National Campaign (PSUNC) in June 2007. This national public education campaign is designed to encourage parents of pre-teens and teens to talk to their children early and often about waiting to have sex. The campaign includes public service announcements (PSA) and print advertisements that guide parents to the 4parents.gov Web site.

The specific aim of this study is to determine the effectiveness of the PSUNC messages by measuring parents' awareness of, reactions to, and receptivity to specific PSUNC advertising. In partnership with Knowledge Networks, an online panel based on a random-digit-dial sample of the full United States population, a probability baseline sample will be selected of 2,000 parents of children aged 10 to 14.

Key research questions include changes in the following outcomes: Perceived risks from teen sexual activity, perceived susceptibility, attitudes towards teen sexual activity, self-efficacy to talk to their child, outcome efficacy, perceived value of delayed sexual activity, and parent-child communication about sex. Parents will self-administer the questionnaire at home on personal computers.

ESTIMATED ONE-YEAR ANNUALIZED BURDEN TABLE

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Fall 2009 Media Tracking Survey (unretained for follow-up).	Parents of children ages 10-14.	1,000	1	24/60	400
Fall 2009 and Spring/Fall 2010 Media Tracking Surveys (retained for follow-up).	Parents of children ages 10-14.	1,000*	2	24/60	800
Total .....	.....	2,000	.....	.....	1,200

\* Subset of original 2,000 collected for Fall 2009 Media Tracking Survey.

**Mary Oliver-Anderson,**

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Assistant Secretary for Administration and Management; Program Support Center; Statement of Organization, Functions and Delegations of Authority**

This notice amends Part (P) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Office of the Assistant

Secretary for Administration and Management (AJ), Program Support Center (P), as last amended at 73 FR 39314, and dated July 9, 2008. This notice will make the following organizational changes in the Program Support Center (PSC): realign the functions of the Administrative Operations Service (PE) and the Enterprise Systems Service (PB), and retitle the Enterprise Systems Service as the Information and Systems Management Service (ISMS) to more accurately reflect the consolidation of