CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-897

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

1.0 MODULE 1: ADMINISTRATIVE INFORMATION AND PRESCRIBING INFORMATION

1.3.5.2 PATENT CERTIFICATION WITH RESPECT TO ANY PATENT WHICH CLAIMS THE DRUG

Paragraph II Certification

Alkermes, Inc. is filing the NDA for Vivitrex® (naltrexone long-acting injection) under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 355 (b)(2)], because the NDA relies in part for approval upon investigations that were not conducted by or for Alkermes and for which Alkermes has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Specifically, the NDA for Vivitrex references and relies in part on the NDA for ReVia (naltrexone hydrochloride) (NDA 18-932).

Alkermes hereby certifies that, in our opinion and to the best of our knowledge, (a) the only patent that claims the drug that is the subject of NDA 18-932 for ReVia -- and on which investigations that are relied upon by Alkermes for approval of the NDA for Vivitrex were conducted or that claims an approved use for such drug and for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.53 -- is United States Patent No. 3,332,950 (the "'950 Patent"), and (b) the '950 has expired.

We note that the NDA for ReVia previously listed in the Orange Book United States Patent No. 3,957,982 (the "'982 Patent") with an expiration date of May 18, 1993. However, Alkermes believes this listing was incorrect, because the '982 Patent is directed to a "method for contraception by the application of combination-type sequential preparations" and does not claim naltrexone or a use of naltrexone that is or was the subject of NDA 18-932 for ReVia. Alkermes believes that the patent number that should have been listed for NDA 18-932 for ReVia is the '950 patent, which does claim naltrexone and also has expired. Alkermes thus makes this Paragraph II certification to the '950 patent.

The NDA for Vivitrex does not seek to rely on data from any other reference listed drugs, and thus we believe that no additional patent certifications are required. *See* 21 C.F.R. 314.50(i); 54 Fed. Reg. 28872, 28875 (July 10, 1989).

EXCLUSIVITY SUMMARY

NDA # 21-897 SUPPL # N/A HFD # 170

Trade Name Vivitrol

Generic Name naltrexone for extended-release injectable suspension

Applicant Name Alkermes

Approval Date, If Known April 13, 2006

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES ☒ NO ☐

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3,SE4, SE5, SE6, SE7, SE8

505(b)(2)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES ☒ NO ☐

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES ☒ NO ☐

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

3 Years

e) Has pediatric exclusivity been granted for this Active Moiety?

YES ☐ NO ☒

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES ☐ NO ☒

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES ☐ NO ☐

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.