CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-372

Administrative Documents

13.0 Patent Information Pursuant to 21 C.F.R. § 314.53

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(b)(1):

TRADE NAME:	To be determined
ACTIVE INGREDIENT:	palonosetron hydrochloride
STRENGTH(S):	0.25 mg
DOSAGE FORM:	Injectable solution

In accordance with 21 C.F.R. § 314.53, the following information is provided for each United States patent that claims the drug product that is the subject of this NDA, a drug substance that is a component of such drug product, or a method of using such drug product, and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product:

PATENT NUMBER:	5,202,333
DATE OF EXPIRATION:	13 April 2010
TYPE OF PATENT:	Drug substance, drug product (composition and formulation), and method of use *inter alia* for the prevention of chemotherapy-induced nausea and vomiting
NAME OF PATENT OWNER:	Syntex (U.S.A.) LLC

The undersigned declares that U.S. Patent Number 5,202,333 covers the drug substance palonosetron, formulations and/or compositions of palonosetron, and/or methods of using palonosetron. The drug product palonosetron is the subject of this NDA for which approval is being sought.

The undersigned certifies that the exclusive right and license to make, have made, develop, register, market, distribute, and sell palonosetron under U.S. Patent Number 5,202,333 is granted by the owner of the patent, Syntex (U.S.A.) LLC, to the applicant of this NDA, Helsinn Healthcare SA, under a licensing agreement between Syntex (U.S.A.) LLC and Helsinn Healthcare SA dated 23 June 1998.

Dario Ceriani

6th August 2002

Dario Ceriani
Senior Manager, Regulatory Affairs
Helsinn Healthcare SA

Date

6th August 2002

Matteo Missaglia
Director, Legal Affairs
Helsinn Healthcare SA

Date

EXCLUSIVITY SUMMARY for NDA # 21-372 SUPPL # N/A
Trade Name Aloxi™
Generic Name palonosetron HCl injection
Applicant Name Helsinn Healthcare S.A. HFD- 180
Approval Date July 25, 2003

PART I: IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain 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 an original NDA? YES/_X/ NO /___/

   b) Is it an effectiveness supplement? YES /___/ NO /X/

      If yes, what type(SE1, SE2, etc.)?

   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 /_X_/ NO /___/

   d) Did the applicant request exclusivity?

      YES /___/ NO /x/

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

      YES /___/ NO /_x/

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use? (Rx to OTC Switches should be answered No - Please indicate as such).

   YES /___/ NO /_x/

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

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

YES /___/ NO /_x/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9 (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 /_x_/

IF THE ANSWER TO QUESTION 1 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS.

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