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May 1, 2007

Division of Dockets Management
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition on behalf of Aurobindo Pharmaceuticals Limited in quadruplicate, pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether the listed drug product has been withdrawn for safety or effectiveness reasons as outlined below:

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Minocycline Hydrochloride, Minocin Capsules EQ 75 mg Base (NDA 050649) manufactured by Triax Pharmaceuticals, Ltd., has been voluntarily withdrawn from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book), contains all FDA-approved drug products. Minocin, Monocycline Hydrochloride Capsules, EQ 75 mg Base, (NDA 050649) appears in the discontinued section of the Orange Book.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an

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ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)). Because the product appears in the discontinued section of the Orange Book, it is requested that the FDA determine whether Triax's decision to discontinue marketing of Minocin, (NDA 050649) Minocycline Hydrochloride Capsules, EQ 75 mg Base was for reasons of safety or effectiveness.

Appropriate pages from the current edition of the Orange Book are enclosed for your ready reference.

A. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

B. Economic Impact

Pursuant to 21 CFR 10.30(b) economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

C. Certification

The undersigned certifies, that to the best of its knowledge and belief, this petition includes all information and views on which the petitioner relies, and that includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,



Anthony C. Celeste
Senior Vice President
Kendle International
On behalf of
Aurobindo Pharmaceuticals, Ltd.

Enclosure

Active Ingredient Search Results from "OB_Disc" table for query on "minocycline."

Appl No	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
<u>063066</u>	MINOCYCLINE HYDROCHLORIDE	CAPSULE; ORAL	EQ 50MG BASE	DYNACIN	MEDICIS
<u>050315</u>	MINOCYCLINE HYDROCHLORIDE	CAPSULE; ORAL	EQ 100MG BASE	MINOCIN	TRIAx PHARMS
<u>050315</u>	MINOCYCLINE HYDROCHLORIDE	CAPSULE; ORAL	EQ 50MG BASE	MINOCIN	TRIAx PHARMS
<u>050649</u>	MINOCYCLINE HYDROCHLORIDE	CAPSULE; ORAL	EQ 75MG BASE	MINOCIN	TRIAx PHARMS
<u>062139</u>	MINOCYCLINE HYDROCHLORIDE	INJECTABLE; INJECTION	EQ 100MG BASE/VIAL	MINOCIN	LEDERLE
<u>050444</u>	MINOCYCLINE HYDROCHLORIDE	INJECTABLE; INJECTION	EQ 100MG BASE/VIAL	MINOCIN	TRIAx PHARMS
<u>050445</u>	MINOCYCLINE HYDROCHLORIDE	SUSPENSION; ORAL	EQ 50MG BASE/5ML	MINOCIN	TRIAx PHARMS
<u>050451</u>	MINOCYCLINE HYDROCHLORIDE	TABLET; ORAL	EQ 100MG BASE	MINOCYCLINE HYDROCHLORIDE	TRIAx PHARMS
<u>050451</u>	MINOCYCLINE HYDROCHLORIDE	TABLET; ORAL	EQ 50MG BASE	MINOCYCLINE HYDROCHLORIDE	TRIAx PHARMS

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through March, 2007

Patent and Generic Drug Product Data Last Updated: April 30, 2007