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APPLICATION NUMBER:

022305Orig1s000

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

NDA#	22-305
PRODUCT	Eye Wash
FORMULATION	Sterile isotonic buffered saline
SUBMISSION DATE	February 22, 2008
SUBMISSION TYPE	Original NDA
SPONSOR	Niagara Pharmaceuticals, Inc., Flamborough, Ontario, Canada
MEDICAL DIVISIONS	DAIOP, DNCE
REVIEWER	Charles R. Bonapace, Pharm.D.
SECONDARY REVIEWER	John A. Lazor, Pharm.D.

CLINICAL PHARMACOLOGY REVIEW

BACKGROUND:
Niagara Pharmaceuticals, Inc., submitted a New Drug Application (NDA) for their sterile [redacted] (b) (4) eye wash solution. The drug product is manufactured in Canada and is distributed in the United States where the formulation is listed as a monographed product. The only difference between the monographed product and the sponsor's product is the method of sterilization. The sponsor uses [redacted] (b) (4) their product whereas the monographed product employs an [redacted] (b) (4) process. The active ingredient of the product is purified water; the product also contains tonicity agents to establish isotonicity with tears, agents for establishing pH and buffering to achieve the same pH as tears, and preservatives. The composition of the sponsor's eye wash product is shown in Table 1.

Table 1. Composition of Niagara Pharmaceuticals Eye Wash

Ingredient	Specification	Target % in Batch
USP Purified Water	[redacted] (b) (4)	[redacted]
Boric Acid NF/EP/USP	[redacted]	[redacted]
Sodium Chloride USP	[redacted]	[redacted]
Sodium Borate NF	[redacted]	[redacted]
[redacted] (b) (4)	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

The sponsor did not provide any information in Module 5 of the submission. Since the drug product is a sterile ophthalmic solution, contains the same active and inactive ingredients in the same concentration as a monographed drug product, and the active ingredient of the drug product is purified water, no additional clinical pharmacology data are necessary. The sponsor is granted a waiver based on CFR 320.22(b)(1). No further clinical pharmacology data are necessary to support the NDA submission.

RECOMMENDATIONS:
The NDA submitted by Niagara Pharmaceuticals is fileable from a clinical pharmacology perspective.

The sponsor is granted a waiver based on CFR 21 320.22(b)(1). No further clinical pharmacology data are required to support the NDA submission.

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Charles R. Bonapace, Pharm.D.
Office of Clinical Pharmacology
Division of Clinical Pharmacology 4

RD/FT Initialed by John A. Lazor, Pharm.D. _____
Division Director
Office of Clinical Pharmacology
Division of Clinical Pharmacology 4

cc:
Division File: NDA 22-305
DNCE (Smith)
DAIOP (Boyd, Harris)
DCP4 (Division File, Lazor, Bonapace)

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/s/

Charles Bonapace
4/16/2008 03:46:39 PM
BIOPHARMACEUTICS

John Lazor
4/17/2008 09:51:36 AM
BIOPHARMACEUTICS