OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA:	208-135
Submission Date(s):	April 30, 2015
PUDFA:	February 29, 2016
Drug	Tetracaine hydrochloride
Product/Formulation; Strength(s)	Tetracaine Hydrochloride Ophthalmic Solution 0.5%
Primary Reviewer	Yongheng Zhang, Ph.D.
Team Leader	Philip Colangelo, Pharm D, Ph D
OCP Division	DCP4
OND Division	DTOP/OAP
Applicant	Alcon Research Ltd
Proposed indication	For procedures requiring a rapid and short-acting topical ophthalmic anesthetic
Dose and Administration	One drop topically in the eye(s) as needed
Submission Type	505(b)(2) ; Standard

SUMMARY

Tetracaine Hydrochloride Ophthalmic Solution 0.5% (STERI UNITS®) is a pre-sterilized ready-to-use topical anesthetic product for ocular use. It is a single-use product intended for procedures in which rapid and short-acting anesthesia is required such as in tonometry, gonioscopy, removal of corneal foreign bodies, conjunctival scraping for diagnostic purposes, suture removal from the cornea, other short corneal, and conjunctival procedures.

Tetracaine Hydrochloride has been marketed, without FDA's approval, as an ophthalmic solution from several manufactures in the United States for more than 45 years as a topical anesthetic in ophthalmologic procedures.

The current submission is a literature-based 505(b)(2) application. The applicant has not conducted any additional clinical studies to support the NDA.

The sponsor did not conduct any clinical pharmacology related studies and requested the waiver of evidence of in vivo bioavailability or bioequivalence. In accordance with the 21 CFR §320.22(e) (see below), the reviewer grants the waiver of evidence of in vivo bioavailability or bioequivalence to this NDA on the basis of the compatibility with the protection of public health due to its long history of clinical use.

21 CFR §320.22(e)
FDA, for good course, may waive a requirement for the submission of evidence of in vivo bioavailability or bioequivalence if waiver is compatible with the protection of the public health……

RECOMMENDATIONS

The Clinical Pharmacology information provided by the Applicant in the NDA is acceptable and the reviewer recommends approval of Tetracaine Hydrochloride Ophthalmic Solution 0.5%.

The reviewer's proposed label changes in Appendix 1 should be forwarded to the sponsor.

Appendix 1. Proposed Labeling with Revisions

The following proposed labeling has been marked with revisions made by the Clinical Pharmacology Reviewer.

(Underline = Clin Pharm reviewer's addition; strikethrough = Clin Pharm reviewer's deletion)

12. CLINICAL PHARMACOLOGY

12.3. Pharmacokinetics

The systemic exposure to tetracaine following topical administration of Tetracaine Hydrochloride Ophthalmic Solution 0.5% has not been studied. Tetracaine hydrochloride is (b) (4) metabolized by plasma pseudocholinesterases and nonspecific esterases in ocular tissues (b) (4).

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/s/

YONGHENG ZHANG
10/13/2015

PHILIP M COLANGELO
10/13/2015