CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-038

CHEMISTRY REVIEW(S)

N21038 on #21-038 HFD-170 K1.3

DRUG NAME: Precedex (dexmedetomidine hcl injection)

APPLICANT: ABBOTT LABORATORIES

REC. 12/28/99

CHEMICAL & THERAPEUTIC CLASS:1S

Review Cycles

Review Cycle: 1 **Submission Date:12-18-98** **Receipt Date:12-18-98** **Goal Date:12-18-99** **Action:AP**	**Review Cycle: 2** **Submission Date:** **Receipt Date:** **Goal Date:** **Action:**
Review Cycle: 3 **Submission Date:** **Receipt Date:** **Goal Date:** **Action:**	**Review Cycle: 4** **Submission Date:** **Receipt Date:** **Goal Date:** **Action:**

CORE REVIEW TEAM MEMBERS

PROJECT MANAGER/ CSO :Susmita Samanta **Phone # & Office Room #:301-827-7410, 9B-45**
MEDICAL:Patricia Hartwell, M.D., M.B.A.
CHEMISTRY:Michael Theodorakis, Ph.D.
PHARM/TOX:Harry Geyer, Ph.D.
BIOPHARMACEUTICS:Suresh Doddapaneni, Ph.D.
BIOMETRICS: Z.Jonathan Ma, Ph.D.
ABUSE LIABILITY: BeLinda A. Hayes, Ph.D.
MICROBIOLOGIST: Patricia Hughes, Ph.D.

Volume 3 of 4

Administrative volume #(s): 1
Clinical volume #(s): 2
CMC volume #(s): 3
Pharmacology/Toxicology volume #(s): 4

ODE II ACTION PACKAGE TABLE OF CONTENTS

Application #21-038

Drug Name: Precedex (dexmedetomidine Hydrochloride injection), 2 mL ampule/2 mL vial, 100 mcg/mL

Applicant: Abbott Laboratories Chem./Ther. Type:1S

CSO/PM: Susmita Samanta Phone: 301-827-7410 HFD-170

Original Application Date: December 18, 1998 Original Receipt Date: December 18, 1998

CURRENT USER FEE GOAL DATE: December 18, 1999 DateTableofContentsCompleted:9/13/99

Section A:	Administrative Information	**X** (completed), **N/A** (not applicable), or Comment
Tab A-1	Action Letter(s) Current Action:AP	X
Tab A-2	Phase 4 Commitments:	
	a. Copy of applicants communication committing to Phase 4	NA
	b. Agency Correspondence requesting Phase 4 Commitments	NA
Tab A-3	FDA revised Labels & Labeling and Reviews: (Separate each version/cycle with a colored sheet)	
	a. Package Insert	X
	b. Immediate Container and Carton Labels	NA
Tab A-4	Original Proposed Labeling	X
Tab A-5	Foreign Labeling:	
	a. Foreign Marketing History	NA
	b. Foreign Labeling and Review(s)	NA
Tab A-6	Labeling and Nomenclature Committee's Tradename Review	X
Tab A-7	Summary Memoranda (e.g., Division Director, Group Leader, Office)	X
Tab A-8	Copy of Patent Statement	X
	Exclusivity Checklist (and any requests for exclusivity)	X
	Debarment Statements	X
Tab A-9	Correspondences, Faxes, & Telecons	X
Tab A-10	Minutes of Meetings:	
	a. End-of-Phase II meeting	NA
	b. Pre-NDA meeting(s)	NA
	c. Filing meeting	X
	d. Other meetings	X
Tab A-11	Advisory Committee Meeting:	
	a. Questions Considered by the committee	NA
	b. List of Attendees	NA
	c. 24 hour alert memorandum	NA

ODE II ACTION PACKAGE TABLE OF CONTENTS (continued)

Application #21-038 Drug Name: Dexmedetomidine HCL

Section B:	Clinical Information	X (completed), N/A (not applicable), or Comment
Tab B-1	Clinical Reviews and Memoranda	X
Tab B-2	Safety Update Reviews	X
Tab B-3	Pediatric Page	X
Tab B-4	Statistical (Clinical) Review and Memoranda	X
Tab B-5	Biopharmaceutics Review and Memoranda	X
Tab B-6	Abuse Liability Review	X
Tab B-7	DSI Audits	X
Tab B-8	Summary of Efficacy (from the summary volume of the application)	NA
Tab B-9	Summary of Safety (from the summary volume of the application)	NA

Section C:	Chemistry, Manufacturing, and Controls (CMC) Information	X (completed), N/A (not applicable), or Comment
Tab C-1	CMC Reviews and Memoranda	X
Tab C-2	DMF Reviews	X
Tab C-3	EA Reviews/FONSI	X
Tab C-4	Micro Review (validation of sterilization)	X
Tab C-5	Statistical Review of drug stability	NA
Tab C-6	Inspection of facilities => Decision:_____ Date:_____	X
Tab C-7	Methods Validation Information	PENDING

Section D:	Pharmacology/Toxicology Information	X (completed), N/A (not applicable), or Comment
Tab D-1	Pharmacology/Toxicology Reviews and Memoranda	X
Tab D-2	Carcinogenicity Review (statistical)	NA
Tab D-3	CAC/Executive Committee Report	NA

ADDITIONAL NOTES:

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

REQUEST FOR A CATEGORICAL EXCLUSION

OF THE REQUIREMENTS OF AN ENVIRONMENTAL IMPACT REPORT

Abbott Laboratories hereby requests a CATEGORICAL EXCLUSION of the requirements of an Environmental Impact Report under the provisions of 21 CFR 25.24.

A CATEGORICAL EXCLUSION may be granted if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the Agency do not establish that at the expected level of exposure, the substance may be toxic to organisms in the environment.

We attach a certification of environmental compliance on the following page.

ABBOTT LABORATORIES

Thomas F. Willer

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