ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION[1]		
NDA # 22-307	NDA Supplement # 000	If NDA, Efficacy Supplement Type:
Proprietary Name: Effient Established/Proper Name: prasugrel Dosage Form: 5 and 10 mg Tablets		Applicant: Eli Lilly and Daiichi Sankyo
RPM: Meg Pease-Fye		Division: Division of Cardiovascular and Renal Products
NDAs: NDA Application Type: ☒ 505(b)(1) ☐ 505(b)(2)		

❖ User Fee Goal Date Action Goal Date (if different)	June 26, 2008, September 26, 2008 July 10, 2009
❖ Actions	
• Proposed action	☒ AP ☐ TA ☐ AE ☐ NA ☐ CR
• Previous actions *(specify type and date for each action taken)*	☒ None
❖ Application[2] Characteristics	

Review priority: ☐ Standard ☒ Priority
Chemical classification (new NDAs only):

☒ Fast Track
☐ Rolling Review
☐ Orphan drug designation
☐ Rx-to-OTC full switch
☐ Rx-to-OTC partial switch
☐ Direct-to-OTC

NDAs: Subpart H
- ☐ Accelerated approval (21 CFR 314.510)
- ☐ Restricted distribution (21 CFR 314.520)

Subpart I
- ☐ Approval based on animal studies

BLAs: Subpart E
- ☐ Accelerated approval (21 CFR 601.41)
- ☐ Restricted distribution (21 CFR 601.42)

Subpart H
- ☐ Approval based on animal studies

☐ Submitted in response to a PMR
☐ Submitted in response to a PMC

Comments: _____

❖ Date reviewed by PeRC *(required for approvals only)*	August 13, 2008
❖ Public communications *(approvals only)*	
• Office of Executive Programs (OEP) liaison has been notified of action	☒ Yes ☐ No

[1] The **Application Information** section is (only) a checklist. The **Contents of Action Package** section (beginning on page 5) lists the documents to be included in the Action Package.

[2] All questions in all sections pertain to the pending application, *i.e.*, if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA. For example, if the application is a pending BLA supplement, then a new *RMS-BLA Product Information Sheet for TBP* must be completed.

• Press Office notified of action (by OEP)	☒ Yes ☐ No
• Indicate what types (if any) of information dissemination are anticipated	☐ None ☒ HHS Press Release ☐ FDA Talk Paper ☐ CDER Q&As ☐ Other
❖ Exclusivity	
• Is approval of this application blocked by any type of exclusivity?	☒ No ☐ Yes
• Is there existing orphan drug exclusivity for the "same" drug or biologic for the proposed indication(s)?	☒ No ☐ Yes
• Is this a single enantiomer that falls under the 10-year approval limitation of 505(u)? *(Note that, even if the 10-year approval limitation period has not expired, the application may be tentatively approved if it is otherwise ready for approval.)*	☒ No ☐ Yes If yes, NDA # and date 10-year limitation expires:
❖ Patent Information (NDAs only)	
• Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought.	☒ Verified
CONTENTS OF ACTION PACKAGE	
❖ Copy of this Action Package Checklist[3]	☒ Included
Officer/Employee List	
❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list *(approvals only)*	☒ Included
Documentation of consent/non-consent by officers/employees	☒ Included
Action Letters	
❖ Copies of all action letters *(including approval letter with final labeling)*	Approved July 10, 2009
Labeling	
❖ Package Insert *(write submission/communication date at upper right of first page of PI)*	
• Most recent division-proposed labeling (only if generated after latest applicant submission of labeling)	
• Most recent submitted by applicant labeling (only if subsequent division labeling does not show applicant version)	
• Original applicant-proposed labeling	Included
• Other relevant labeling (e.g., most recent 3 in class, class labeling), if applicable	Included
❖ Medication Guide/Patient Package Insert/Instructions for Use *(write submission/communication date at upper right of first page of each piece)*	☒ Medication Guide ☐ Patient Package Insert

[3] Fill in blanks with dates of reviews, letters, etc.

	☒ Instructions for Use ☒ None
• Most-recent division-proposed labeling (only if generated after latest applicant submission of labeling)	
• Most recent submitted by applicant labeling (only if subsequent division labeling does not show applicant version)	
• Original applicant-proposed labeling	
• Other relevant labeling (e.g., most recent 3 in class, class labeling), if applicable	
❖ Labels (**full color** carton and immediate-container labels) *(write submission/communication date at upper right of first page of each submission)*	
• Most-recent division proposal for (only if generated after latest applicant submission)	
• Most recent applicant-proposed labeling	Included
❖ Labeling reviews *(indicate dates of reviews and meetings)*	☐ RPM ☐ DMEDP ☒ DRISK ☒ DDMAC ☐ CSS ☒ Other reviews SEALD
❖ Proprietary Name • Review(s) *(indicate date(s))* • Acceptability/non-acceptability letter(s) *(indicate date(s))*	May 29, 2008
Administrative / Regulatory Documents	
❖ Administrative Reviews *(e.g., RPM Filing Review[4]/Memo of Filing Meeting) (indicate date of each review)*	Filing Review 02.28.2008 PM Overview 07.21.2009
❖ NDAs only: Exclusivity Summary *(signed by Division Director)*	☒ Included
❖ Application Integrity Policy (AIP) Status and Related Documents www.fda.gov/ora/compliance_ref/aip_page.html	
• Applicant in on the AIP	☐ Yes ☒ No
❖ Pediatric Page *(approvals only, must be reviewed by PERC before finalized)*	☒ Included
❖ Debarment certification (original applications only): verified that qualifying language was not used in certification and that certifications from foreign applicants are cosigned by U.S. agent *(include certification)*	☒ Verified, statement is acceptable
❖ Postmarketing Requirement (PMR) Studies	☒ Yes
• Outgoing communications *(if located elsewhere in package, state where located)*	
• Incoming submissions/communications	July 10, 2009 Available in EDR
❖ Postmarketing Commitment (PMC) Studies	☒ Yes
• Outgoing Agency request for postmarketing commitments *(if located elsewhere in package, state where located)*	
• Incoming submission documenting commitment	July 10, 2009 Available in EDR
❖ Outgoing communications *(letters (except previous action letters), emails, faxes, telecons)*	☒ Included
❖ Internal memoranda, telecons, etc.	☒ Included

[4] Filing reviews for other disciplines should be filed behind the discipline tab.

❖ Minutes of Meetings	
• PeRC *(indicate date; approvals only)*	☒ August 13, 2008
• Pre-Approval Safety Conference *(indicate date; approvals only)*	☒ Multiple meetings with OSE
• Regulatory Briefing *(indicate date)*	☒ September 5, 2008 ☒ March 16, 2009
• Pre-NDA/BLA meeting *(indicate date)*	☒ May 30, 2007
• EOP2 meeting *(indicate date)*	☒ August 4, 2004
• Other (e.g., EOP2a, CMC pilot programs)	Pre Phase 3: October 16, 2003 EoP2A: December 9, 2004 CMC Pilot: November 20, 2006
❖ Advisory Committee Meeting(s)	☒ Yes
• Date(s) of Meeting(s)	February 3, 2009
• 48-hour alert or minutes, if available	
Decisional and Summary Memos	
❖ Office Director Decisional Memo *(indicate date for each review)*	☒ July 10, 2009
Division Director Summary Review *(indicate date for each review)*	☒ April 25, 2009
Cross-Discipline Team Leader Review *(indicate date for each review)*	☒ July 10, 2008 January 9, 2009 July 6, 2009 (2) July 7, 2009
Clinical Information[5]	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) *(indicate date for each review)*	See CDTL dates
• Clinical review(s) *(indicate date for each review)*	June 19, 2008 December 28, 2008 December 31, 2008 February 2, 2009 February 4, 2009 May 6, 2009 May 13, 2009 June 10, 2009 July 8, 2009
• Social scientist review(s) (if OTC drug) *(indicate date for each review)*	☒ None
❖ Safety update review(s) *(indicate location/date if incorporated into another review)*	Adressed in Dr. Hicks' April 28, 2008 review
❖ Financial Disclosure reviews(s) or location/date if addressed in another review	Addressed on page 11 of Dr. Hicks' April 28, 2008 review
❖ Clinical reviews from other clinical areas/divisions/Centers *(indicate date of each review)*	Oncology 05.27.2009
❖ Controlled Substance Staff review(s) and Scheduling Recommendation *(indicate date of each review)*	☒ Not needed

[5] Filing reviews should be filed with the discipline reviews.

❖ Risk Management • Review(s) and recommendations (including those by OSE and CSS) *(indicate date of each review and indicate location/date if incorporated into another review)* • REMS Memo *(indicate date)* • REMS Document and Supporting Statement *(indicate dates of submissions)*	June 12, 2008 (epi) June 16, 2008 (secondary epi) October 7, 2008 (OSE) January 8, 2009 (OSE) January 21, 2009 (DMEPA) April 14, 2009 (OSE) June 8, 2009 January 21, 2009 March 12, 2009 May 4, 2209 May 21, 2009 June 12, 2009 June 25, 2009 July 9, 2009
❖ DSI Clinical Inspection Review Summary(ies) *(include copies of DSI letters to investigators)*	June 5, 2008
Clinical Microbiology ☒ None	
❖ Clinical Microbiology Team Leader Review(s) *(indicate date for each review)*	☐ None
Clinical Microbiology Review(s) *(indicate date for each review)*	☐ None
Biostatistics ☐ None	
❖ Statistical Division Director Review(s) *(indicate date for each review)*	March 14, 2009
Statistical Team Leader Review(s) *(indicate date for each review)*	☒ None
Statistical Review(s) *(indicate date for each review)*	April 29, 2008 May 2, 2008 May 7, 2008 (genomic) June 4, 2008 June 17, 2008
Clinical Pharmacology ☐ None	
❖ Clinical Pharmacology Division Director Review(s) *(indicate date for each review)*	☒ None
Clinical Pharmacology Team Leader Review(s) *(indicate date for each review)*	☒ None
Clinical Pharmacology review(s) *(indicate date for each review)*	May 28, 2008 June 11, 2008 June 27, 2008
❖ DSI Clinical Pharmacology Inspection Review Summary *(include copies of DSI letters)*	June 6, 2008
Nonclinical ☐ None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) *(indicate date for each review)*	June 19, 2008
• Supervisory Review(s) *(indicate date for each review)*	☒ None
• Pharm/tox review(s), including referenced IND reviews *(indicate date for each review)*	April 28, 2008 February 2, 2009
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer *(indicate date for each review)*	☐ None
❖ Statistical review(s) of carcinogenicity studies *(indicate date for each review)*	February 19, 2008
❖ ECAC/CAC report/memo of meeting	July 24, 2003 Included in P/T review, page34

❖ DSI Nonclinical Inspection Review Summary *(include copies of DSI letters)*	☒ None requested
CMC/Quality ☐ None	
❖ CMC/Quality Discipline Reviews	
• ONDQA/OBP Division Director Review(s) *(indicate date for each review)*	☒ None
• Branch Chief/Team Leader Review(s) *(indicate date for each review)*	August 31, 2008
• CMC/product quality review(s) *(indicate date for each review)*	May 14, 2008 August 29, 2008 September 23, 2008 June 19, 2009
❖ Microbiology Reviews • NDAs: Microbiology reviews (sterility & pyrogenicity)	☒ Not needed
❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer *(indicate date of each review)*	☐ None
❖ Environmental Assessment (check one) (original and supplemental applications)	
☒ Categorical Exclusion *(indicate review date)(all original applications and all efficacy supplements that could increase the patient population)*	p. 216 of May 14, 2008 review
☐ Review & FONSI *(indicate date of review)*	
☐ Review & Environmental Impact Statement *(indicate date of each review)*	
❖ NDAs: Methods Validation	☒ Completed ☐ Requested ☐ Not yet requested ☐ Not needed
❖ Facilities Review/Inspection	
• NDAs: Facilities inspections (include EER printout) *(date completed must be within 2 years of action date)*	Date completed: September 6, 2008 ☒ Acceptable ☐ Withhold recommendation

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/s/

Margaret Pease-Fye
7/21/2009 01:48:15 PM