

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-017

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-564/S-045
NDA 50-575/S-034
NDA 50-597/S-041
NDA 50-720/S-017
NDA 50-726/S-016
NDA 50-725/S-020
NDA 50-755/S-005
NDA 50-590/S-047
NDA 50-658/S-015

GlaxoSmithKline
Attention: Stephen M. LoCastro
Assistant Director, Regulatory Affairs
1250 South Collegeville Road
P.O. Box 5089
Collegeville, Pennsylvania 19426-0989

Dear Mr. LoCastro:

Please refer to your supplemental new drug application dated June 14, 2002, received June 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin[®] Tablets (50-564), Augmentin[®] 4:1 Powder for Oral Suspension (50-575), Augmentin[®] Chewable Tablets (50-597), Augmentin[®] BID Tablets (50-720), Augmentin[®] 7:1 Powder for BID Oral Suspension (50-725), Augmentin[®] BID Chewable Tablets (50-726), Augmentin ES-600[™] 14:1 Powder for Oral Suspension (50-755), Timentin[®] (50-590), and Timentin[®] for Injection in Plastic Container, PL 2040 (50-658). We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental new drug applications provide for a change to the release specification for clavulanate potassium bulk, specifically, increases the upper assay limit from the current value of

We completed our review of these supplemental new drug applications. These supplements are approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Susmita Samanta, M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

David B. Katague, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective Drug Products, (HFD-520)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

David Katague
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