

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**20-386/S-032**

**Correspondence**



NDA 20-386/S-032

Merck & Co., Inc.  
Attention: Jeffrey R. Tucker, M.D.  
Sumneytown Pike  
P.O. Box 4, BLA-20  
West Point, PA 19486

Dear Dr. Tucker:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Cozaar (losartan potassium) Tablets

NDA Number: 20-386

Supplement number: S-032

Date of supplement: July 25, 2002

Date of receipt: July 26, 2002

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on September 24, 2002 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:

Center for Drug Evaluation and Research  
Division of Cardio-Renal Drug Products, HFD-110  
Attention: Division Document Room  
5600 Fishers Lane  
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Cardio-Renal Drug Products, HFD-110  
Attention: Division Document Room  
1451 Rockville Pike  
Rockville, Maryland 20852

If you have any questions, please call:

Mr. Edward Fromm  
Regulatory Project Manager  
(301) 594-5332

Sincerely yours,

/S/

Natalia A. Morgenstern  
Chief, Project Management Staff  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Zelda McDonald  
8/5/02 02:45:39 PM  
For Natalia Morgenstern.