DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

Dear Application Holder:

The attached report form is being furnished for your convenience in complying with the "NDA- Field Alert" reporting requirements of Section 314.81 (b)(1)(i) and (ii), as codified in Title 21 of the Code of Federal Regulations, effective May 23, 1985:

"314.81 Other postmarketing reports.

(a) Applicability. Each applicant shall make the reports for each of its approved applications and abbreviated applications required under this section and sections 505 (j) and 507 (g) of the act.

(b) Reporting Requirements. The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports:

(1) NDA-Field Alert Report. The applicant shall submit information of the following kinds about distributed drug products and articles to the FDA District office that is responsible for the facility involved within three working days of receipt by the applicant. The information may be provided by telephone or other rapid communication means, with prompt written followup. The report and its mailing cover should be plainly marked: 'FDA-Field Alert Report.'

(i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specifications established for it in the application."

In this context, PLEASE NOTE that the information required under 21 CFR 314.81 *SHOULD NOT* be submitted with reports of adverse drug reactions as described under 21 CFR 314.80, the regulation dealing with the postmarketing reporting of adverse drug experiences.

Accordingly, please submit the required *21 CFR 314.81* information within three (3) working days to the "NDA-Field Alert Report"coordinator in your jurisdictional FDA District Office, who will also be available to answer any questions that you may have regarding your reports.

For your convenience, the addresses and telephone numbers of all FDA district offices are listed on the reverse side.

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FDA/ORA FIELD ADDRESSES

New York District (NYK-DO)
158-15 Liberty Ave.
Jamaica, NY 11433
Tel: 718-340-7000

New England District (NWE-DO)
One Montvale Ave., 4th Floor
Stoneham, MA 02180
Tel: 781-279-1675

Buffalo Branch (NYK-DO)
300 Pearl St., Suite 100
Buffalo, NY 14202
Tel: 716-551-4461

Philadelphia District (PHI-DO)
900 U.S. Customhouse
2nd & Chestnut Sts.
Philadelphia, PA 19106
Tel: 215-597-4390

Baltimore District (BLT-DO)
6000 Metro Dr.
Baltimore, MD 21215
Tel: 410-779-5454

New Jersey District (NWJ-DO)
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
Tel: 973-526-6015

Cincinnati District (CIN-DO)
6751 Steger Dr.
Cincinnati, OH 45237-3097
Tel: 513-679-2700

Chicago District (CHI-DO)
550 W. Jackson Bldv.
15th Floor
Chicago, IL 60661
Tel: 312-353-5863

Detroit District (DET-DO)
300 River Pl. Drive, Suite 5900
Detroit, MI 48207-3179
Tel: 313-393-8100

Minneapolis District (MIN-DO)
212 Third Ave. South
Minneapolis, MN 55401
Tel: 612-334-4100

Atlanta District (ATL-DO)
60 Eighth St., NE
Atlanta, GA 30309
Tel: 404-347-3151 (ATL-DO)
704-344-6116 (Charlotte, R.P.)

Nashville Branch (NOL-DO)
297 Plus Park Blvd.
Nashville, TN 37217
Tel: 615-781-5392

New Orleans District (NOL-DO)
6600 Plaza Dr., Suite 400
New Orleans, LA 70127
Tel: 504-253-4500

Florida District (FLA-DO)
555 Winderley Place
Suite 500
Maitland, FL 32751
Tel: 407-475-4700

San Juan District (SJN-DO)
466 Fernandez Juncos Ave.
San Juan, PR 00901-3223
Tel: 787-729-6854

Dallas District (DAL-DO)
4040 North Central Expswy.
Suite 300
Dallas, TX 75204
Tel: 214-253-5200

Denver District (DEN-DO)
11510 West 80th St.
Denver, CO 80225-0087
Tel: 303-236-3000

Kansas City District (KAN-DO)
11510 West 80th St.
Lenexa, KS 66214-3338
Tel: 913-752-2442

St. Louis Branch (STL-BR)
12 Sunnen Dr., Suite 122
St. Louis, MO 63143-3800
Tel: 314-645-1167

San Francisco District (SAN-DO)
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Tel: 510-337-6846

Seattle District (SEA-DO)
22201 23rd Dr., SE
Bothell, WA 98021-4421
Tel: 425-483-4971

Los Angeles District (LOS-DO)
19900 MacArthur Blvd.
Suite 300
Irvine, CA 92612-2445
Tel: 949-798-7600

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Form Approved: OMB No. 0910-0001. Expiration Date: 3/31/05
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

NDA-FIELD ALERT REPORT

TO: *(NAME AND ADDRESS OF DISTRICT)*

TYPE OF REPORT ☐ Initial ☐ Follow-Up ☐ Final

In accordance with Section 314.81 (b)(1)(i) and (ii) of the New Drug and Antibiotic Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1. NDA/ANDA - ANTIBIOTIC FORM 5/6 NO. | NDC No.
2. GENERIC NAME OF DRUG PRODUCT
3. TRADE NAME *(if any)* OF DRUG PRODUCT
4. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)
5. LOT NUMBER(S)
6. EXPIRATION DATE(S) OF DRUG PRODUCTS
7. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER
8. SOURCE(S) OF REPORT
9. PROBLEM(S) ASSOCIATED WITH DRUG PRODUCT
10. PROBABLE CAUSE(S) OF PRODUCT PROBLEM(S)
11. CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)
12. REMARKS

NOTE: FOR ITEMS 9, 10, 11, AND 12, SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT

NAME AND MAILING ADDRESS *(Include ZIP Code)*

NAME AND TITLE OF AUTHORIZED REPRESENTATIVE | TELEPHONE *(Include Area Code)*

SIGNATURE OF AUTHORIZED REPRESENTATIVE | DATE SUBMITTED

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An federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to:

Food and Drug Administration
CDER, HFD-336
11919 Rockville Pike
Rockville, MD 20852