DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

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 follow-up. 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.

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: 781-596-7700

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., Suite 101
Baltimore, MD 21215
Tel: 410-779-5454

New Jersey District (NWJ-DO)
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
Tel: 973-331-4902

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

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

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

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

New Orleans District (NOL-DO)
U.S. FDA
404 BNA Drive, Suite 500
Nashville, TN 37217-2597
Tel: 615-366-7813

Denver Federal Center
6th Avenue & Kipling Streets
Bldg. 20, Entrance W10
PO Box 25087
Denver, CO 80225-0087
Tel: 303-236-3087

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: 787-474-9500

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

Minneapolis District (MIN-DO)
250 Marquette Avenue, #600
Minneapolis, MN 55401
Tel: 612-334-4100

Kansas City District (KAN-DO)
11630 W. 80th Street
Lenexa, KS 66214-3340
Tel: 913-752-2446

San Francisco District
(SAN-DO)
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Tel: 510-337-6820

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

Form Approved: OMB No. 0910-0001. Expiration Date: May 31, 2011. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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 Application Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1. NDA/ANDA	2. NDC No.
3. GENERIC NAME OF DRUG PRODUCT	4. TRADE/BRAND NAME *(if any)* OF DRUG PRODUCT
5. FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED	6. FEI/CFN
7. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)	
8. LOT NUMBER(S)	
9. EXPIRATION DATE(S) OF DRUG PRODUCTS	
10. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER	
11. HOW WAS PROBLEM DISCOVERED	
12. STATE PROBLEM(S)	
13. ROOT CAUSE(S) OF PROBLEM(S)	
14. CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)	
15. REMARKS	

NOTE: 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

FARS FORM INSTUCTIONS

Please fill in the location to which the form will be submitted. See Appendix for list of FDA district office addresses.

Place check in the box which indicates whether the report is an initial, follow-up or final report. If the report is solely an initial report – please place the estimated time the final report will be submitted in the remarks section (15). If the report is an initial and final report i.e., no further submission to FDA is contemplated - check both boxes. If the report is a follow-up or final report - please place the date of the initial report in the remarks section (15).

Enter the following information:

(1) A/NDA of the drug product involved. A/NDA numbers should match those at www.fda.gov/cder/ob/default.htm.

(2) NDC number of the product(s) involved. This includes the labeler code, product code, and if appropriate the package code. (For prescription drugs, valid NDC numbers may be found at www.fda.gov/cder/ndc.) If the product does not have an NDC number, please enter “None” and explain why in the remarks section (15).

(3) Generic name of product(s).

(4) Trade/Brand name of product(s).

(5) Name and physical address of the firm where the problem occurred. For example, if the problem occurred at a labeling site or repacking site, list that site here. For problems involving stability, place the site of the product manufacturer. If the problem involves the bulk active pharmaceutical ingredient (API), supply the name and complete address of the bulk supplier. If the site is a foreign location, include the country name.

(6) Firm Establishment Identification (FEI) number, or Central Filing Number (CFN) of the site listed in (5). If the FEI/CFN is unknown, leave blank.

(7) Dosage form of product (www.fda.gov/cder/ndc/tbldosag.txt), strength of product(s) in appropriate units (www.fda.gov/cder/ndc/tblunit.txt), and package size(s).

(8) Lot number(s) of product(s) involved.

(9) Expiration date(s) of product(s).

(10) Date of discovery/notification of problem by applicant.

(11) Description of how the problem was discovered, e.g., routine product testing, consumer report, etc.

(12) Nature of problem identified.

(13) Root cause of problem.

(14) Corrective actions taken to prevent the recurrence of the problem or remove the product from the marketplace.

(15) Remarks pertinent to FARS report or underlying issue.

Reporting Establishment section - Enter name, address, responsible person, and submission date of the report. Please include the relationship to the product, e.g., NDA holder, manufacturer, etc.

A 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857