Designer note: This form file is a "layout only" design proof. It has ***no*** entry fields or functionality and has not been optimized for 508 compliance. All those elements will be added or updated & maintained in the final "508 compliant" **Adobe "LiveCycle" PDF** file after FDA approves this revised layout design.

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 section 505 (k) 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, via email submit button, the required 21 CFR 314.81 information within three (3) working days to the "NDA-Field Alert Report" coordinator in the FDA district office where the facility is located as specified on page 1, Box 1. Reports involving foreign facilities can be reported to the jurisdictional FDA district office, where the firm's attorney, agent or other authorized official resides or maintains a place of business in the US. (21 CFR 314.50).

For your convenience, the addresses and telephone numbers of all FDA district offices are listed on page ii. The e-mail submit button is located on the bottom of the last form page of the form.

FDA/ORA FIELD ADDRESSES

Select ***one*** primary address by marking the box next to an address below.

When filling out this form in Adobe Reader:

- The selected address automatically will be placed in the upper right area on form page 1, *and*
- its email address will be the "To" addressee in the email generated by the submit button on the last form page.

☐ New York District
158-15 Liberty Ave.
Jamaica, NY 11433
Tel: 718-340-7000
ORANYKFAR@fda.hhs.gov

☐ New England District (NWE-DO)
One Montvale Ave., 4th Floor
Stoneham, MA 02180
Tel: 781-587-7500
ORANWEFAR@fda.hhs.gov

☐ Philadelphia District (PHI-DO)
Rm 900 U.S. Customhouse
200 Chestnut St.
Philadelphia, PA 19106
Tel: 215-597-4390
ORAPHIFAR@fda.hhs.gov

☐ Baltimore District (BLT-DO)
6000 Metro Dr., Suite 101
Baltimore, MD 21215
Tel: 410-779-5455
ORABLTFAR@fda.hhs.gov

☐ New Jersey District (NWJ-DO)
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
Tel: 973-331-4900
ORANWJFAR@fda.hhs.gov

☐ Cincinnati District (CIN-DO)
6751 Steger Dr.
Cincinnati, OH 45237-3097
Tel: 513-679-2700
ORACINFAR@fda.hhs.gov

☐ Chicago District (CHI-DO)
550 W. Jackson Blvd.
15th Floor
Chicago, IL 60661
Tel: 312-353-5863
ORACHIFAR@fda.hhs.gov

☐ Detroit District (DET-DO)
300 River Place, Suite 5900
Detroit, MI 48207-3179
Tel: 313-393-8100
ORADETFAR@fda.hhs.gov

☐ Atlanta District (ATL-DO)
60 Eighth St., NE
Atlanta, GA 30309
Tel: 404-253-2263
ORAATLFAR@fda.hhs.gov

☐ New Orleans District (NOL-DO)
U.S. FDA
404 BNA Drive, Suite 500
Nashville, TN 37217-2597
Tel: 251-344-8208, ext. 105
ORANOLFAR@fda.hhs.gov

☐ Denver District (DEN-DO)
Denver Federal Center, Bldg 20
6th Avenue & Kipling Streets
PO Box 25087
Denver, CO 80225-0087
Tel: 303-236-3097
ORADENFAR@fda.hhs.gov

☐ Florida District (FLA-DO)
555 Winderley Place Suite 200
Maitland, FL 32751
Tel: 407-475-4700
ORAFLAFAR@fda.hhs.gov

☐ San Juan District (SJN-DO)
466 Fernandez Juncos Ave.
San Juan, PR 00901-3223
Tel: 787-474-9500
ORASJNFAR@fda.hhs.gov

☐ Dallas District (DAL-DO)
4040 North Central Expswy.
Suite 300
Dallas, TX 75204
Tel: 214-253-5200
ORADALFAR@fda.hhs.gov

☐ Minneapolis District (MIN-DO)
250 Marquette Avenue, #600
Minneapolis, MN 55401
Tel: 612-334-4100
ORAMINFAR@fda.hhs.gov

☐ Kansas City District (KAN-DO)
11630 W. 80th Street
Lenexa, KS 66214-3340
Tel: 913-752-2769
ORAKANFAR@fda.hhs.gov

☐ San Francisco District (SAN-DO)
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Tel: 510-337-6790
ORASANFAR@fda.hhs.gov

☐ Seattle District (SEA-DO)
22215 26th Ave SE
Suite 210
Bothell WA 98021
Tel: 425-302-0435
ORASEAFAR@fda.hhs.gov

☐ Los Angeles District (LOS-DO)
19701 Fairchild
Irvine, CA 92612-2506
Tel: 949-608-2900
ORALOSFAR@fda.hhs.gov

Form Approved: OMB No. 0910-0001, Expiration Date: December 31, 2017. See PRA Statement on last form page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

NDA-FIELD ALERT

To: *(Name and Address of District, per page ii selection)*

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Type of Report *(Select all that apply)*
MANDATORY
☐ 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. Firm Name and Address Where Problem Occurred

Firm Name

Address *(Street address, P.O. box, company name c/o)*

City | State/Province/Region

Country | ZIP or Postal Code

2. DUNS/FEI Number *(Fill out both numbers if known.)*

DUNS Number
Up to 15 characters, alpha-numeric

FEI Number
Up to 15 characters, alpha-numeric

Put DUNS # first and FEI second, to be consistent with the order shown in #2 text label, but will switch if you confirm you really want FEI to be first.

3. NDA/ANDA /Other Number *(Select only one number type. If NDA or ANDA selected, then also fill in Number entry; skip Number if Other.)*

☐ NDA ☐ ANDA ☐ Other Number: _____

4. NDC Number(s) *(If more than one NDC number, separate with semi-colons.)*

5. Generic Name of Drug Product

6. Trade/Brand Name (if any) of Drug Product

7.a. Dosage Form

7.b. Dosage Strength and Package Size *(If more than one dosage strength & package size, separate with semi-colons.)*

8. Lot Number(s) and Expiration Date(s) *(If more than one lot number and expiration date, separate with semi-colons.)*

9. Date when notified about problem(s) or when problem(s) first became known to application holder

10. How was problem discovered?

11. State Problem(s)

12. Describe Root Cause(s) of Problem(s)

13. Describe Corrective Action(s) Taken (if any) to Prevent Recurrence of Problem(s)

14. Remarks

NOTE: *Separate tables and graphs may be attached if desired.*

REPORTING ESTABLISHMENT

Name and Mailing Address

Reporting Establishment Name

Address *(Street address, P.O. box, company name c/o)*

City | State (or Province or Region)

Country | ZIP (or Postal) Code

DUNS/FEI Number *(Fill out both numbers if known.)*

DUNS Number
Up to 15 characters, alpha-numeric

FEI Number
Up to 15 characters, alpha-numeric

To be consistent with 2014 version, it will be mandatory on the final fillable file to include *at least* one of the above numbers.

Name and Title of Authorized Representative

Telephone Number *(Include area code)*

Email Address

Date Submitted

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 8 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

"An 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 number."

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

SUBMIT

Button does not work in this "layout only" design file.