DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0291
Expiration Date: 9/30/2018
(See PRA Statement below)

MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

When do I use this form?

- You were hurt or had a bad side effect (including new or worsening symptoms) after taking a drug or using a medical device or product.
- You used a drug, product, or medical device incorrectly which could have or led to unsafe use.
- You noticed a problem with the quality of the drug, product, or medical device.
- You had problems with how a drug worked after switching from one maker to another maker.

Don't use this form to report:

- Vaccines – report problems to the Vaccine Adverse Event Reporting System (VAERS).
- Investigational drugs or medical devices (those being studied) – report problems to your doctor or to the contact person listed in the clinical trial.

Will the information I report be kept private?

The FDA recognizes that privacy is an important concern, so you should know:

- We ask only for the name and contact information of the person filling out the form in case we need more information.
- Your name and contact information may be shared with the company that makes the product to help them better understand the problem you are reporting, unless you request otherwise (see Section E).

What types of products should I use this form for?

- Drugs, including prescription or over-the-counter medicines, and biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- Medical devices, including any health-related kit, test, tool, or piece of equipment (such as breast implants, pacemakers, diabetes glucose-test kits, hearing aids, breast pumps, and many others)
- Nutrition products including vitamins and minerals, herbal remedies, infant formulas, medical foods, such as those labeled for people with a specific disease or condition
- Cosmetics such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos
- Foods (including beverages and ingredients added to foods)

Are there specific instructions for filling out the form?

- Fill in as much information as possible and send in the report even if you do not have all the information.
- You can fill out this form yourself or have someone fill it out for you. If you need help, you may want to talk with your health professional.
- Feel free to include or attach an image of the product. Please do not send the products to the FDA.

How will I know the FDA has received my form?

- You will receive a reply from the FDA after we receive your report. We will personally contact you only if we need additional information.
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How can I contact the FDA if I have questions?

Toll-free line: 1-800-332-1088
www.fda.gov/reportinghelp
To report online: www.fda.gov/medwatch/report.htm

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 30 minutes 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:

OMB Statement: "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 ADDRESS.

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Expiration Date: 9/30/2018
(See PRA Statement on preceding general information page)

Note: *For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.*

Section A – About the Problem

What kind of problem was it? *(Check all that apply)*

- ☐ Were hurt or had a bad side effect *(including new or worsening symptoms)*
- ☐ Used a product incorrectly which could have or led to a problem
- ☐ Noticed a problem with the quality of the product
- ☒ Had problems after switching from one product maker to another maker

Did any of the following happen? *(Check all that apply)*

- ☐ Hospitalization – admitted or stayed longer
- ☐ Required help to prevent permanent harm *(for medical devices only)*
- ☒ Disability or health problem
- ☐ Birth defect
- ☐ Life-threatening
- ☐ Death *(include date)(dd-mmm-yyyy)*: _____
- ☐ Other serious/important medical incident *(Please describe below)*

Date the problem occurred *(dd-mmm-yyyy)*

08-Aug-2016

Tell us what happened and how it happened. *(Include as many details as possible)*

I have been having allergic rhinitis for over 5 years and I have been using First Pharmaceutical's steroid nasal spray, as prescribed by my family doctor. First Pharmaceutical's nasal spray has been working well for me for the past 5 years. On 8/8/2016 I went to the pharmacy to pick up my refill and I was given a different generic brand nasal spray by XYZ

List any relevant tests or laboratory data if you know them. *(Include dates)*

None

For a problem with a product, including

- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

Go to Section B

For a problem with a medical device, including

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

Go to Section C (Skip Section B)

For more information, visit *http://www.fda.gov/MedWatch*

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Section B – About the Products

Name of the product as it appears on the box, bottle, or package *(Include as many names as you see)*
XYZ Pharmaceutical nasal spray

Name of the company that makes (or compounds) the product
XYZ Pharmaceutical

Is the Product Compounded? *(Your health professional may be able to help you identify whether the drug was compounded.)*	☐ Yes ☐ No	Is the Product Over-the-Counter?	☐ Yes ☐ No

Expiration date *(dd-mmm-yyyy)*	Lot number	NDC number
Jul-2013	610877	50383-700-16

Strength *(for example, 250 mg per 500 mL or 1 g)*	Quantity *(for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)*	Frequency *(for example, twice daily or at bedtime)*	How was it taken or used *(for example, by mouth, injection, or on the skin)?*
50mcg/dose	One spray in each nostril	Twice daily	Nasal

Date the person first started taking or using the product *(dd-mmm-yyyy)*: 01-Jan-2012
Date the person stopped taking or using the product *(dd-mmm-yyyy)*: 20-Jul-2016

Why was the person using the product? *(such as, what condition was it supposed to treat)*
Allergic rhinitis

Did the problem stop after the person reduced the dose or stopped taking or using the product? ☐ Yes ☐ No

Did the problem return if the person started taking or using the product again?
☐ Yes ☐ No ☐ Didn't restart

Do you still have the product in case we need to evaluate it? *(Do not send the product to FDA. We will contact you directly if we need it.)*
☒ Yes ☐ No

Go to Section D (Skip Section C)

Section C – About the Medical Device

Name of medical device

Name of the company that makes the medical device

Other identifying information *(The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)*

Was someone operating the medical device when the problem occurred?
☐ Yes
☐ No

If yes, who was using it?
☐ The person who had the problem
☐ A health professional *(such as a doctor, nurse, or aide)*
☐ Someone else *(Please explain who)*

For implanted medical devices ONLY *(such as pacemakers, breast implants, etc.)*

Date the implant was put in *(dd-mmm-yyyy)*	Date the implant was taken out *(If relevant) (dd-mmm-yyyy)*

Go to Section D

Section D – About the Person Who Had the Problem

Person's Initials	Sex	Age *(specify unit of time for age)*	Date of Birth *(dd-mmm-yyyy)*	Weight *(Specify lbs or kg)*
AF	☐ Female ☒ Male	66 ☒ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)	19-May-1945	☐ lb ☐ kg

Race/ Ethnicity	Ethnicity *(Choose only one)*	Race *(Choose all that apply)*
	☐ Hispanic/Latino ☐ Not Hispanic/Latino	☐ American Indian or Alaskan Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White

List known medical conditions. *(Such as diabetes, high blood pressure, cancer, heart disease, or others)*
No other medical conditions

Please list all allergies (*such as to drugs, foods, pollen or others*)
Seasonal allergy

List any other important information about the person (*such as smoking, pregnancy, alcohol use, etc.*)
I am a retired construction worker.

List all current prescription medications and medical devices being used.
None

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
None

Go to Section E

Section E – About the Person Filling Out This Form

We will contact you only if we need additional information.

Last name	First name
F	Alfred

Number/Street	City and State/Province
111 Street	New York, NY

Country	ZIP or Postal code
USA	111111

Telephone number	Email address	Today's date *(dd-mmm-yyyy)*
100-555-1212	Af@xxxx.com	01-Dec-2016

Did you report this problem to the company that makes the product (the manufacturer/compounder)? ☐ Yes ☒ No

If you do NOT want your identity disclosed to the manufacturer, place an 'X' in this box: ☒

Send This Report By Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA. Mail or fax the form to: MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852; FAX: 800-332-0178 (toll-free).

Thank you for helping us protect the public health.

For more information, visit *http://www.fda.gov/MedWatch*

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Pharmaceutical. The product was the same 50mcg/dose with the same directions, one spray in each nostril twice daily, as the previous brand I used before.

Within the first several days of use, I noticed that the XYZ Pharmaceutical's nasal spray was not working as well as the previous generic brand I was using before. I said to my wife that the new nasal spray was more like distilled water instead of medicine. I continued to use the medication as directed, but continued to have the persistent and troublesome post-nasal drainage that I did not have when using the First Pharmaceutical spray. After several months of use, my wife encouraged me to speak with my pharmacist about the possibility that this generic brand was "different" than my other previous brand that worked for me.
The pharmacist called my doctor and got a phone refill for the First Pharmaceutical brand of steroid nasal spray. I started using the original brand that evening, and within three to four days, I noticed that the beneficial effect had returned.