# APPENDIX C

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See OMB statement on reverse

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page ____ of ____

| Mfr report # |
|---|
| UF/Dist report # |
| FDA Use Only |

## A. Patient information

| 1. Patient identifier | 2. Age at time of event: or Date of birth: | 3. Sex | 4. Weight |
|---|---|---|---|
| In confidence | | ☐ female ☐ male | ____ lbs or ____ kgs |

## B. Adverse event or product problem

1. ☐ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)

2. **Outcomes attributed to adverse event** (check all that apply)
   - ☐ death ____ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ____

| 3. Date of event (mo/day/yr) | 4. Date of this report (mo/day/yr) |
|---|---|
| | |

5. **Describe event or problem**

6. **Relevant tests/laboratory data**, including dates

7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

## C. Suspect medication(s)

1. **Name** (give labeled strength & mfr/labeler, if known)
   #1
   #2

| 2. Dose, frequency & route used | 3. Therapy dates (if unknown, give duration) from/to (or best estimate) |
|---|---|
| #1 | #1 |
| #2 | #2 |

| 4. Diagnosis for use (indication) | 5. Event abated after use stopped or dose reduced |
|---|---|
| #1 | #1 ☐ yes ☐ no ☐ doesn't apply |
| #2 | #2 ☐ yes ☐ no ☐ doesn't apply |

| 6. Lot # (if known) | 7. Exp. date (if known) | 8. Event reappeared after reintroduction |
|---|---|---|
| #1 | #1 | #1 ☐ yes ☐ no ☐ doesn't apply |
| #2 | #2 | #2 ☐ yes ☐ no ☐ doesn't apply |

9. **NDC #** – for product problems only (if known)
   – –

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

## D. Suspect medical device

1. **Brand name**

2. **Type of device**

| 3. Manufacturer name & address | 4. Operator of device |
|---|---|
| | ☐ health professional ☐ lay user/patient ☐ other: ____ |

6.
- model # ____
- catalog # ____
- serial # ____
- lot # ____
- other # ____

| 5. Expiration date (mo/day/yr) |
|---|
| 7. If implanted, give date (mo/day/yr) |
| 8. If explanted, give date (mo/day/yr) |

9. **Device available for evaluation?** (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

## E. Initial reporter

| 1. Name & address | phone # |
|---|---|
| | |

| 2. Health professional? | 3. Occupation | 4. Initial reporter also sent report to FDA |
|---|---|---|
| ☐ yes ☐ no | | ☐ yes ☐ no ☐ unk |

PLEASE TYPE OR USE BLACK INK

FDA

FDA Form 3500A

**Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.**

# Medication and Device Experience Report

(continued)

Refer to guidelines for specific instructions

**Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.**

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Public Health Service • Food and Drug Administration

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FDA Use Only

## F. For use by user facility/distributor–devices only

1. **Check one** ☐ user facility ☐ distributor
2. **UF/Dist report number**
3. **User facility or distributor name/address**
4. **Contact person**
5. **Phone Number**
6. **Date user facility or distributor became aware of event** (mo/day/yr)
7. **Type of report** ☐ initial ☐ follow-up # ____
8. **Date of this report** (mo/day/yr)
9. **Approximate age of device**
10. **Event problem codes** (refer to coding manual)
   patient code ____ – ____ – ____
   device code ____ – ____ – ____
11. **Report sent to FDA?** ☐ yes ____ (mo/day/yr) ☐ no
12. **Location where event occurred** ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ nursing home ☐ ambulatory surgical facility ☐ outpatient treatment facility ☐ other: ____ specify
13. **Report sent to manufacturer?** ☐ yes ____ (mo/day/yr) ☐ no
14. **Manufacturer name/address**

## G. All manufacturers

1. **Contact office – name/address** (& initial site for devices)
2. **Phone number**
3. **Report source** (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☐ other: ____
4. **Date received by manufacturer** (mo/day/yr)
5. (A)NDA # ____ IND # ____ PLA # ____ pre-1938 ☐ yes OTC product ☐ yes
6. **If IND, protocol #**
7. **Type of report** (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ initial ☐ follow-up # ____
8. **Adverse event term(s)**
9. **Mfr. report number**

## H. Device manufacturers only

1. **Type of reportable event** ☐ death ☐ serious injury ☐ malfunction (see guidelines) ☐ other: ____
2. **If follow-up, what type?** ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. **Device evaluated by mfr?** ☐ not returned to mfr. ☐ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code: ____
4. **Device manufacture date** (mo/yr)
5. **Labeled for single use?** ☐ yes ☐ no
6. **Evaluation codes** (refer to coding manual)
   method ____ – ____ – ____ – ____
   results ____ ____ ____ ____
   conclusions ____ – ____ – ____ – ____
7. **If remedial action initiated, check type** ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/ adjustment ☐ other: ____
8. **Usage of device** ☐ initial use of device ☐ reuse ☐ unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ **Additional manufacturer narrative** and/or 11. ☐ **Corrected data**



**Please DO NOT RETURN this form to this address.**