
Guidance for Industry

Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application

DRAFT GUIDANCE

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For questions regarding this draft document contact Kathleen Frost 301-796-2380.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

**October 2007
Clinical/Medical**

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

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I. INTRODUCTION

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This document provides guidance to industry on postmarketing serious adverse event reporting for nonprescription (over-the-counter (OTC)) human drug products marketed without an approved application. In particular, this document gives guidance on (1) the minimum data elements that should be included in a serious adverse event report, (2) the label that should be included with the report, (3) reporting formats for paper and electronic submissions, and (4) how and where to submit the reports.

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FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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II. BACKGROUND

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Public Law 109-462, the Dietary Supplement and Nonprescription Drug Consumer Protection Act, was signed by the President on December 22, 2006.² Public Law 109-462 amends the Federal Food, Drug, and Cosmetic Act (the Act) to add safety reporting requirements for OTC drug products that are marketed without an approved application under section 505 of the Act

¹ This guidance has been prepared by the Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

² See : <http://www.fda.gov/cder/regulatory/default.htm#Legislation>
(http://www.fda.gov/cder/regulatory/public_law_109462.pdf).

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38 (21 U.S.C. 355).³ Before the enactment of Public Law 109-462, only those OTC drugs marketed
39 with an application approved under section 505 of the Act (21 U.S.C. 355) were subject to
40 mandatory postmarketing safety reporting requirements.⁴ As required by section 2(e)(3) of
41 Public Law 109-462, we are issuing this guidance to describe the minimum data elements for the
42 required reports.⁵ This guidance also describes relevant policies and procedures for making
43 these reports.

44
45 The manufacturer, packer, or distributor⁶ whose name (under section 502(b)(1) of the Act (21
46 U.S.C. 352(b)(1))) appears on the label of an OTC drug marketed in the United States without an
47 approved application (referred to as the *responsible person*) must submit to FDA any report
48 received of a serious adverse event associated with such drug when used in the United States,
49 accompanied by a copy of the label on or within the retail package of such drug (section
50 760(b)(1) of the Act). In addition, the responsible person must submit follow-up reports of new
51 medical information related to a submitted serious adverse event report that is received within 1
52 year of the initial report (section 760(c)(2) of the Act). Serious adverse event reports received
53 through the address or telephone number described on the product label, as well as all follow-up
54 reports of new medical information, must be submitted to FDA no later than 15 business days
55 after a report of a serious adverse event or the new medical information is received by the
56 responsible person (section 760(c)(1) and 760(c)(2) of the Act). We recommend that all serious
57 adverse event reports received by the responsible person be submitted to FDA within 15 business
58 days of receipt.⁷

³ Section 760 of the Act (21 U.S.C. 379aa), as amended, provides for mandatory safety reporting for OTC human drug products not subject to applications approved under section 505 of the Act (new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Accordingly, these new requirements apply to all OTC drug products marketed under the OTC Drug Review, including those not yet subject to a final monograph. These reporting requirements become effective December 22, 2007.

⁴ Postmarketing safety reporting requirements for drugs marketed under an approved application, including OTC drugs, are set forth at 21 CFR 314.80 and 314.98.

⁵ Public Law 109-462 states that “Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance on the minimum data elements that should be included in a serious adverse event report as described under the amendments made by this Act” (section 2(e)(3)). Public Law 109-462 also requires certain postmarketing safety reports for dietary supplements. The Center for Food Safety and Applied Nutrition is issuing a separate guidance on reporting for dietary supplements.

⁶ Under section 760(b)(2) of the Act, a retailer whose name appears on the label as a distributor may, by agreement, authorize the manufacturer or packer of the OTC drug to satisfy its safety reporting obligations under the Act.

⁷ Section 760(c)(1) of the Act, which contains the 15-day deadline for submitting serious adverse event reports to FDA, expressly applies to serious adverse event reports resulting from information received by the responsible person through the address or telephone number on the product label. Although the Act does not expressly provide a timeframe for serious adverse event reports that the responsible person receives by other means (such as by e-mail or fax), the reporting of such adverse events is required by the plain language of section 760(b)(1) (providing that the responsible person “shall submit . . . any report received of a serious adverse event associated with such drug when used in the United States . . .” (emphasis added)). Prompt submission of serious adverse event reports is important for public health reasons. Delayed reporting of some serious adverse events to FDA solely because of the medium through which the adverse event was reported to the responsible person would lessen the effectiveness of adverse event reporting as a tool for FDA to detect and alert the public to possible safety problems. Therefore, the agency strongly recommends that all serious adverse event reports received by the responsible person, regardless of the means by which the report was received, be submitted within the same timeframe as reports received by phone or mail, i.e., within 15 business days of their receipt by the responsible person.

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59 The information on data elements included in this document is consistent to the extent possible
60 with guidance on data elements for a safety report for applicants of approved NDAs, ANDAs,
61 and antibiotic applications; manufacturers of marketed prescription drugs for human use without
62 approved NDAs or ANDAs; and licensed manufacturers of approved biologic product license
63 applications (BLAs).⁸

64

III. MINIMUM DATA ELEMENTS FOR AN INDIVIDUAL CASE SAFETY REPORT (ICSR)

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A. Initial ICSR Submission

69

70 As discussed in section II of this document, section 760(b)(1) of the Act, as amended, requires
71 responsible persons to submit to FDA any report received of a serious adverse event associated
72 with the use of an OTC drug marketed in the United States without an approved application
73 when the product is used in the United States. The person who first notifies the responsible
74 person about an adverse drug event is the *reporter*. Reporters can include patients, relatives of
75 patients, consumers, doctors, pharmacists, other health care practitioners, or other individuals.

76

77 Reporters convey information on adverse events to the responsible person by various means,
78 including phone, the Internet, fax, e-mail, or regular mail. Based on the information from the
79 reporter and any other information received or obtained on the adverse event, the responsible
80 person completes an ICSR in one of the formats described in section V of this document and
81 submits it to FDA.

82

83 To complete an ICSR, responsible persons should provide all known or reasonably known
84 applicable elements on FDA Form 3500A or its electronic equivalent identified by FDA for
85 electronic reporting. Applicable elements on FDA Form 3500A include all sections except those
86 identified as *for device manufacturers only* (i.e., all sections except D, F, and H). See Appendix
87 1 for the specific elements on FDA Form 3500A.

88

89 The quality of reports of serious adverse events submitted to FDA is critical for appropriate
90 evaluation of the relationship between the product and adverse events.⁹ FDA recommends that
91 responsible persons make a reasonable attempt to obtain complete information for case
92 assessment during initial contacts and subsequent follow-up and encourages responsible persons
93 to use trained health care practitioners to query reporters. Computer-assisted interview
94 technology, targeted questionnaires, or other methods developed to target specific events can

⁸ See the guidance for industry, *Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report*, available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. In March 2001 (66 FR 14391), the Agency also made available a draft guidance document on *Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines*. When finalized, the guidance will provide recommendations on this topic. We update guidances periodically. To make sure you have the most recent version of guidances, check the CDER guidance page at <http://www.gda.gov/cder/guidance/index.htm>.

⁹ See the guidance for industry on *Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment*, available at <http://www.fda.gov/cder/guidance/index.htm>.

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95 help focus the line of questioning. When the reporter is a patient or consumer, the responsible
96 person should attempt to contact the health care practitioner familiar with the patient's adverse
97 event, with the patient/consumer's permission, to obtain further medical information and to
98 retrieve relevant medical records, if appropriate.
99

100 FDA considers all of the applicable elements on FDA Form 3500A or its electronic equivalent as
101 critical for case assessment. In order for FDA to avoid duplication, interpret significance,
102 facilitate follow-up, and detect fraud, at a minimum, the four data elements listed in the bullets
103 below should be included in any serious adverse event report for an OTC drug product that is
104 marketed without an approved application:
105

- 106 • an identifiable patient
- 107 • an identifiable reporter
- 108 • a suspect drug
- 109 • a serious adverse event or fatal outcome

110
111 The responsible person should actively seek information on any minimum data element not
112 initially provided by the reporter and wait to submit a report on the incident to FDA until the
113 information is obtained. The responsible person should maintain records of the event
114 information and its efforts to obtain the basic elements for an individual report in its files.
115

116 The responsible person should actively seek follow-up information for the purposes of
117 completing all the applicable elements for an ICSR. The responsible person should document
118 its efforts to obtain additional relevant information. If the responsible person documents these
119 efforts, then the responsible person must maintain the documentation for 6 years and allow FDA
120 to access the records (section 760(e) of the Act).
121

1. Identifiable Patient

122
123
124 To have an identifiable patient, there should be enough information to indicate the
125 existence of a specific patient or consumer. One or more of the following automatically
126 qualifies a patient as identifiable: age (or age category, e.g., adolescent, adult, elderly),
127 gender, initials, date of birth, name, or patient identification number. A report stating that
128 "an elderly woman had anaphylaxis" or "a young man experienced anaphylaxis" would
129 be sufficient. If a report received by the responsible person refers to groups of unknown
130 size, such as "some" or "a few" college students got anaphylaxis, the responsible person
131 should follow up to find out the number and then submit a separate report to FDA for
132 each identifiable patient. The responsible person should distinguish each patient so that it
133 is clear that each ICSR is not a duplicate report of a single adverse event.
134

135 Patients should not be identified by name or address when reporting to FDA. Instead, the
136 responsible person should assign a code (e.g., patient initials) to each ICSR. The
137 assigned code will permit the responsible person to cross-reference with identifying
138 information and contact information in the event follow-up is sought.
139

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2. *Identifiable Reporter*

A reporter is the person who first notifies the responsible person about the serious adverse event and can be the patient, consumer, or some other person (e.g., doctor, family member). Reports that are received from a third party who has only limited information or lacks first-hand knowledge about the serious adverse event (e.g., “my neighbor told me that a friend became seriously ill after taking Product X”), or that are made anonymously should not be submitted to FDA as an ICSR unless there is sufficient information for the responsible person to follow-up, such as a phone number or e-mail address. If the reporter requests that the responsible person not forward their contact information to FDA, the responsible person can submit a report without specific identification of the reporter, as long as the responsible person keeps the contact information on file so that it could contact the reporter either upon request by FDA or on its own initiative. For these reports, the responsible person should fill in the *reporter identity fields* in an ICSR with a statement such as “Requested Anonymity.”

3. *Suspect Drug*

A suspect drug is easily ascertained when no other drug products have been used by the patient. However, if a serious adverse event involves multiple drug products that are manufactured, packaged, or distributed by the same responsible person, the responsible person should submit only one ICSR, according to the safety reporting requirements applicable to the drug product considered most suspect by the reporter.¹⁰ If the reporter views each product as equally suspect, the responsible person should submit only one ICSR, according to the safety reporting requirements applicable to the drug product that is first alphabetically. In either case, the ICSR would include information on all suspect drug products with one manufacturer report number.

If the serious adverse event is associated with an OTC drug product(s) marketed without an approved application and a dietary supplement(s) that is also manufactured, packaged, or distributed by the same responsible person, and the reporter views each product as suspect, the responsible person should submit one ICSR about the serious adverse event to both CDER and to CFSAN. The ICSR should identify both suspect products and use one manufacturer report number.

If a serious adverse event involves multiple suspect drug products that were manufactured, packaged or distributed by more than one responsible person (e.g., manufacturer A and B), and if the event is reported to one of the responsible persons

¹⁰ See section 760 of the Act (for OTC drug products marketed without an approved application), 21 CFR 310.305 (for prescription drug products marketed without an approved application), 21 CFR 314.80 (for drug products marketed under an NDA), 21 CFR 314.98 (for drug products marketed under an ANDA), 21 CFR 314.540 (for drug products approved under Subpart H), or 21 CFR 600.80 (for drug products marketed under a BLA).

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178 (manufacturer A), then that responsible person (manufacturer A) should submit an ICSR
179 to FDA on the serious adverse event that describes detailed information, including
180 identification of manufacturer B's product(s). In such a case, manufacturer A should
181 send manufacturer B a copy of the submitted FDA Form 3500A, including manufacturer
182 A's report number. In this case, manufacturer B need not submit to FDA information
183 originally submitted to the Agency by manufacturer A. In this case, if manufacturer B
184 receives additional information about the serious adverse event, manufacturer B should
185 submit the new medical information as a separate ICSR with its own manufacturer report
186 number and reference manufacturer A's report number in the narrative section (i.e.,
187 section B.5 for reports submitted using FDA Form 3500A or its equivalent in the
188 electronic format).

189 4. *Serious Adverse Event*

192 *A serious adverse event*, as defined in section 760(a)(3) of the Act, must have one or
193 more of the following patient outcomes or, based on reasonable medical judgment,
194 require a medical or surgical intervention to prevent one of the following patient
195 outcomes:

- 196 • death
- 197 • a life-threatening experience
- 198 • inpatient hospitalization
- 199 • a persistent or significant disability or incapacity
- 200 • a congenital anomaly or birth defect
- 201
- 202

203 Inpatient hospitalization includes initial admission to the hospital on an inpatient basis,
204 even if released the same day, and prolongation of an existing inpatient hospitalization.

205
206 Examples of serious adverse events that based on reasonable medical judgment should be
207 treated medically or surgically to prevent one of the listed outcomes, include allergic
208 bronchospasm that calls for intensive treatment in an emergency room or at home, blood
209 dyscrasias or convulsions that do not result in inpatient hospitalization, or the
210 development of drug dependency or drug abuse.

211
212 For reporting purposes, a serious adverse event should, at a minimum, be described in
213 terms of signs (including abnormal laboratory findings), symptoms, or disease diagnosis
214 for purposes of reporting. Thus, a report stating that a patient "experienced unspecified
215 injury" or a patient "suffered irreparable damages" would not be specific enough. If the
216 reporter does not provide any signs, symptoms, or diagnosis, responsible persons should
217 obtain more information from that person, the patient, or (with the patient's permission)
218 medical professionals who treated the patient. A report of a death, even without
219 information about events that led to the death, meets the minimum description of a
220 serious adverse event and should be reported to FDA. Responsible persons should also
221 provide any available information on the event(s) that led to the death.

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222 As part of the serious adverse event report, we encourage, as appropriate, attachment of
223 the following: (1) hospital discharge summaries, (2) autopsy reports, (3) relevant
224 laboratory data, and (4) other critical clinical data.
225

226 The ICSR must be submitted within 15 business days of receipt of the report of the serious
227 adverse event received through the address or phone number on the label (section 760(c)(1) of
228 the Act). The date the responsible person receives the four basic elements (i.e., identifiable
229 patient, identifiable reporter, suspect drug, serious adverse event) is Day 0 of the 15-business-day
230 time clock and should be entered into item G.4 of FDA Form 3500A or its electronic equivalent.
231

232 Reports of serious adverse events received by a responsible person in which the initial reporter
233 identifies the suspect drug as one manufactured, packaged, or distributed by another responsible
234 person should be promptly forwarded to that other responsible person. A responsible person
235 who receives a report of an adverse event regarding one of its products from another responsible
236 person must submit an ICSR to FDA within the same timeframe applicable to any report
237 received from a reporter, unless the ICSR has already been submitted to FDA by the first
238 responsible person (see section III.A.3 of this document).
239

240 If a responsible person does not initially receive sufficient data for a report, but subsequently
241 receives additional information completing the four basic elements concerning a serious adverse
242 event, then an initial report should be submitted within 15 business days of the date the
243 additional information was received, with the date that the additional information was received
244 entered into item G.4 of FDA Form 3500A or its electronic equivalent.
245

B. Submission of New Medical Information (Follow-up Reports)

246
247
248 The responsible person must submit a follow-up report when new medical information related to
249 a submitted serious adverse drug event report is received by the responsible person within 1 year
250 of the initial report (section 760(c)(2) of the Act). Follow-up reports must be submitted no later
251 than 15 business days after the new information is received by the responsible person (section
252 760(c)(2) of the Act). Responsible persons should provide a current, comprehensive
253 understanding of the serious adverse drug event, rather than providing only the changes and/or
254 updates to the initial report. Relevant information from the initial report should be combined
255 with the follow-up information to present an accurate and comprehensive, but concisely written,
256 description of the event as it is understood at the time of the follow-up report. This description
257 and note of any changes or corrections to any fields should be provided in section B.5 for reports
258 submitted using FDA Form 3500A or its equivalent in the electronic format.
259

260 Any information from the initial report later found to be inaccurate should not be repeated in the
261 follow-up report. All new information, including correction of previously submitted inaccurate
262 information that is included in a follow-up report, should be highlighted. To highlight new
263 information or corrections included in follow-up reports submitted using FDA Form 3500A, use
264 an asterisk or underline the new information. For example, if new dose information is received,
265 it should be included in field C.1, and a statement such as “Dose has been updated,” underlined
266 or highlighted with an asterisk, should be included in section B.5. Any unchanged attachments

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267 submitted with an initial report (e.g., hospital discharge summaries, lab results) should not be
268 resubmitted with a follow-up report.

269
270 If a new, serious adverse event occurs that is associated with the initial serious adverse event, a
271 follow-up report should be submitted. However, if the new, serious adverse event is not
272 associated with the initial serious adverse event (e.g., occurs after a subsequent administration of
273 the product), an initial report with a new manufacturer report number should be submitted for the
274 new, serious adverse event and the manufacturer report number for the original serious adverse
275 event should be included in the narrative section of the report. In these cases, the responsible
276 person should consider the clinical relevance of the serious adverse events to each other when
277 determining whether an initial report or follow-up report should be submitted.

278
279 Follow-up reports should use the same identification number as used in the initial ICSR (i.e., the
280 number in section G.9 for reports submitted using FDA Form 3500A). This allows the initial
281 ICSR and all of its follow-up reports to be linked in FDA's Adverse Event Reporting System
282 database (AERS) (see section V.B of this document for information on AERS). The
283 identification number used to submit follow-up reports to FDA should be the same as the
284 identification number used in the initial ICSR, even if the responsible person reassigns
285 identification numbers to internal files for submitted ICSRs (e.g., if duplicate reports are
286 consolidated, or data handling procedures are changed). No characters should be added to the
287 initial manufacturer report number on submitted reports to denote that the report is a follow-up
288 or to denote the sequence of the reports. The initial identification number of the follow-up
289 reports should continue to be used, but the reassigned internal identification number can be noted
290 in the narrative section of the follow-up report (e.g., "This event has been reassigned Company A
291 ID number COA12345").

292

IV. SUBMITTING THE LABEL

294

295 Each ICSR of a serious adverse event associated with an OTC drug marketed in the United
296 States without an approved application must be accompanied by a copy of the current label on or
297 within the retail package of the drug (see section 760(b)(1) of the Act). The labels submitted
298 with the report should include the full outer carton/container label and immediate container label,
299 including the Drug Facts panel and the principal display panel. For ICSRs submitted on paper
300 (FDA Form 3500A), responsible persons should submit legible paper copies of these labels, no
301 smaller than actual size, as an attachment to the form. For ICSRs submitted in an electronic
302 format, labels should be submitted in an appropriate electronic format that FDA can process,
303 review, and archive (see section V.B of this document). A copy of the label should not be
304 resubmitted with a follow-up report unless there have been changes to the label since the initial
305 submission.

306

V. REPORTING FORMATS FOR PAPER OR ELECTRONIC SUBMISSIONS

308

309 As described in section III of this document, under sections 760(b)(1) and (c)(2) of the Act,
310 responsible persons must submit initial and follow-up ICSRs of serious adverse events associated
311 with the use of OTC drugs marketed in the United States without an approved application when

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312 the products are used in the United States. In addition, as described in section IV of this
313 document, under section 760(b)(1) of the Act, the report must be accompanied by a copy of the
314 label on or within the retail package of the drug. Responsible persons should use an FDA Form
315 3500A or an electronic format to submit the ICSRs, as described below.

316
317 This section describes how to (1) acquire, generate, complete, and submit an FDA Form 3500A
318 for reporting ICSRs and (2) submit ICSRs and the copies of the label in an electronic format.

A. Paper Submission (FDA Form 3500A)

1. Acquiring Copies of FDA Form 3500A

324 The form can be acquired from:

- 325 • Appendix 1 of this guidance
- 326 • the Internet at <http://www.fda.gov/medwatch/getforms.htm> or
- 327 <http://www.fda.gov/opacom/morechoices/fdaforms/OC.html>
- 328 • CDER's Division of Drug Information:
- 329 –By e-mail: druginfo@fda.hhs.gov
- 330 –By phone: 1-888-INFO-FDA
- 331 1-888 463-6332 or (301) 827-4570
- 332 –By mail: Division of Drug Information
- 333 5600 Fishers Lane, HFD-240
- 334 Rockville, MD 20857

2. Generating Copies of FDA Form 3500A

344 Copies of the form can be generated by:

- 345 • Photocopying a blank FDA Form 3500A
- 346 • Producing a printed facsimile of FDA Form 3500A
- 347 –Generated by Fillable Forms Software at
- 348 http://www.fda.gov/medwatch/safety/FDA-3500A_Fillable_08-16-2006.pdf and
- 349 included in Appendix 1.
- 350 –Generated by commercial software that can be used after the format is agreed to in
- 351 advance by FDA. For details see item 4 at
- 352 http://www.fda.gov/medwatch/report/instruc_10-13-06.htm#obtain.
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3. *Completing FDA Form 3500A*

All FDA Form 3500A submissions should be legibly printed or typewritten and completed with a minimum font size of 8 point. Legible photostatic copies can be submitted. However, visual contrast and paper opacity should be adequate to ensure clear readable archival images. A form reporting a serious adverse event associated with the use of an OTC drug product should have “OTC Product” checked in field G5 of the form. FDA encourages responsible persons to use an FDA assigned national drug code (NDC) number as the product identifier in field C9 of the form. The NDC number is the most useful product identifier for FDA. Alternatively, if the suspect OTC drug product does not have an FDA-assigned NDC number, any other standard product identification code or number should be entered in field C9. For additional information, see Instructions on completing FDA Form 3500A at http://www.fda.gov/medwatch/report/instruc_10-13-06.htm.

4. *Submitting FDA Form 3500A*

Completed FDA Form 3500A should be sent to:

Central Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Do not include a cover letter with the submission; all information should be included in the FDA Form 3500A and in attachment(s), if any.

B. *Electronic Submission*

The AERS system is a computerized information database designed to support FDA's postmarketing safety surveillance program for all marketed drug and biologic products excluding blood components and vaccine products. FDA has implemented the regulatory and infrastructure changes for full-scale implementation to accommodate electronic submissions of ICSRs and ICSR attachments.

To fulfill the submission requirements of section 760 of the Act, responsible persons can complete and submit electronic ICSRs with the full outer carton/container and immediate container label, including the Drug Facts panel and principal display panel, as electronic ICSR attachments. Contact the AERS Electronic Submission Coordinator at the following number(s) or e-mail address to discuss your intent to submit ICSRs and ICSR attachments in an electronic format:

Phone: 301-770-9299
FAX: 301-770-6614

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402 E-MAIL: AERSESUB@cderr.fda.gov

403

404 For information on electronic submission of ICSRs and ICSR attachments, see

405 <http://www.fda.gov/cder/aerssub/default.htm>.

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406 **APPENDIX 1: FDA FORM 3500A**

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408 FDA Form 3500A: <http://www.fda.gov/medwatch/SAFETY/3500A.pdf>

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3500A.pdf (40
KB)

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413 Fillable version of the form plus instructions:

414 http://www.fda.gov/medwatch/safety/FDA-3500A_Fillable_08-16-2006.pdf

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