Guidance for Industry

Providing Regulatory Submissions in Electronic Format — Postmarketing Periodic Adverse Drug Experience Reports

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document send an e-mail (CDER and CBER) to aersesub@cder.fda.gov, or telephone (CDER) Randy Levin, 301-594-5411, or (CBER) Michael Fauntleroy, 301-827-5132.

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

June 2003
Electronic Submission

Guidance for Industry

Providing Regulatory Submissions in Electronic Format — Postmarketing Periodic Adverse Drug Experience Reports

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

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Guidance for Industry[1] Providing Regulatory Submissions in Electronic Format — Postmarketing Periodic Adverse Drug Experience Reports

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 it 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.

I. INTRODUCTION

This is one in a series of guidance documents intended to assist applicants making regulatory submissions in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA). Agency guidance documents on electronic submissions will be updated regularly to reflect the evolving nature of the technology and the experience of those using this technology.

This guidance discusses general issues related to the electronic submission of postmarketing periodic adverse drug experience reports for (1) drug products marketed for human use with new drug applications (NDAs)[2] and abbreviated new drug applications (ANDAs)[3] and (2) therapeutic

[1] This guidance has been prepared by the Offices of Information Technology (OIT) and Drug Safety (ODS) in the Center for Drug Evaluation and Research (CDER) in cooperation with the Office of Information Management (OIM) and Division of Epidemiology, Office of Biostatistics and Epidemiology (OBE) in the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA).

The Commissioner has announced a consolidation of the CDER/CBER review functions for therapeutic products. Once the consolidation has been completed, we will review those guidances that have been affected by the transfer of functions for possible revision.

[2] Human drug products subject to postmarketing safety reporting regulations at 21 CFR 314.80

[3] Human drug products subject to postmarketing safety reporting regulations at 21 CFR 314.98

and blood products marketed for human use with biologics license applications (BLAs).[4] This guidance does ***not*** apply to vaccines, whole blood, or components of whole blood.

In January 1999, the FDA issued the guidance for industry *Providing Regulatory Submissions in Electronic Format — General Considerations*. The *General Considerations Guidance* discusses issues common to all types of electronic regulatory submissions, such as acceptable file formats, physical media and submission procedures.[5] In May 2001, the FDA issued the draft guidance for industry *Providing Regulatory Submissions in Electronic Format — Postmarketing Expedited Safety Reports.* The *Expedited Safety Reports* draft guidance discusses issues related to the electronic submission of postmarketing expedited individual case safety reports (ICSRs) and attachments to ICSRs (ICSR attachments) (i.e., 15-day alert reports). We are preparing the final guidances. In cases in which the same subject matter is discussed in the *Expedited Safety Reports* draft guidance and this guidance (e.g., submission types identified in public docket number 92S-0251, E2B/E2BM field B2 "Reaction(s)/event(s)"), the proposed recommendations in this guidance supercede the recommendations provided in the *Expedited Safety Reports* draft guidance of 2001. The references below to the *Expedited Safety Reports* guidance refer to that guidance when it is issued in final form.

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

II. GENERAL ISSUES

Regulations for submission of postmarketing periodic adverse drug experience reports to CDER and CBER are described in 21 CFR 314.80(c)(2) and 600.80(c)(2). This section briefly addresses some general issues related to the electronic submission of these reports and contains recommendations for submitting reports in electronic form to CDER and CBER. If you wish to submit reports in another manner than that described below, we recommend you contact the appropriate division.

A. Parts of a Postmarketing Periodic Adverse Drug Experience Report

For the purpose of electronic submissions, we have divided the postmarketing periodic adverse drug experience report into three parts: (1) ICSRs,[6] (2) ICSR attachments, if applicable, and (3) descriptive information.[7] The descriptive information includes the

[4] Human biological products subject to postmarketing safety reporting regulations at 21 CFR 600.80

[5] The FDA is in the process of revising the *General Considerations Guidance of 1999* and will issue a draft guidance for public comment at that time.

[6] See 21 CFR 314.80(c)(2)(ii)(b) and 600.80(c)(2)(ii)(B) for the requirement to submit ICSRs in postmarketing periodic adverse drug experience reports.

[7] See 21 CFR 314.80(c)(2)(ii)(a) and (c) and 600.80(c)(2)(ii)(A) and (C) for the requirement to submit descriptive information in postmarketing periodic adverse drug experience reports.

narrative summary and analysis of the information in the report (i.e., periodic ICSRs and ICSR attachments), an analysis of the 15-day alert reports submitted during the reporting interval (i.e., expedited ICSRs and ICSR attachments), and the history of actions taken since the last report because of adverse drug experiences (e.g., labeling changes, studies initiated).

B. The Archival Copy

We have identified in public docket number 92S-0251 postmarketing periodic ICSRs with and without ICSR attachments as submission types that we can accept in an electronic format.[8] You can provide these ICSRs in electronic format in place of the currently required paper copy.[9] If you choose to submit these ICSRs to us in electronic format, you should not also submit them to us in paper format. We do not want duplicate reports.

Once we have identified in public docket number 92S-0251 that we can accept the descriptive information portion of postmarketing periodic adverse drug experience reports in electronic format, you can provide them to us electronically in place of the currently required paper copy.

C. Notification of Initial Electronic Submission

In the *Expedited Safety Reports Guidance*, applicants are advised to notify the Adverse Event Reporting System (AERS) electronic submission coordinator at aersesub@cder.fda.gov prior to the first time that an ICSR is submitted electronically to the FDA. This applies to all ICSRs, whether expedited or periodic. It is not necessary to contact the AERS electronic submission coordinator prior to submitting descriptive information for a postmarketing periodic adverse drug experience report electronically.

D. Sending in the Submission

1. Periodic ICSRs and ICSR attachments

The *Expedited Safety Reports* guidance, when finalized, will provide recommendations for submitting ICSRs and ICSR attachments for a postmarketing periodic adverse drug experience report. As described in the *Expedited Safety Reports* guidance, you can send ICSRs to the FDA using either the FDA's Electronic Data Interchange (EDI) gateway or physical media (e.g., CD-ROM, digital tape). Sending your ICSRs through the EDI gateway will allow the most efficient processing of these reports by the FDA and will provide you

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[8] See www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm

[9] See 21 CFR 11.2(b) for electronic submission requirements and 21 CFR 314.80(f) and 600.80(f) for the requirement to submit postmarketing ICSRs on paper (i.e., on FDA Form 3500A)

with an electronic acknowledgement that your transmission has been received by the FDA (see section II.E. of this guidance).

The *Expedited Safety Reports* guidance also indicates that you should send ICSR attachments to the FDA on physical media.[10] If you send your ICSR to the FDA using the EDI gateway and the ICSR has attachments, you should not resend the ICSR on the physical medium with the ICSR attachments. We do not want duplicate reports sent to us (e.g., using the EDI gateway and on physical media).

You should not mix electronic and paper submission formats for ICSRs and their attachments. We are not able to process ICSRs with ICSR attachments that are electronic/paper hybrids. If you send an ICSR to us electronically (i.e., via EDI gateway or on physical media), the attachments for this ICSR also would be sent to us electronically (i.e., on physical media). The converse is also true. If you send ICSR attachments to us on paper, the ICSR associated with these attachments would also be sent to us on paper.

2. Descriptive information

You should provide the descriptive information for a postmarketing periodic adverse drug experience report on physical media as described in the *General Considerations Guidance.*[11] We will be able to accept the descriptive information electronically once we have identified it in public dockt number 92S-0251

3. Physical media

Physical media should be submitted to the FDA as described in the *General Considerations Guidance*. Additional information specific to postmarketing periodic safety reports are provided in this section.

A physical medium containing periodic ICSRs and/or ICSR attachments should be submitted protected (e.g., in a sleeve, jewel case, physical media mailer) to the FDA. The protected physical medium should be attached securely to a jacket (e.g., notebook, binder). This physical medium should not contain any expedited ICSRs and/or ICSR attachments.[12]

A physical medium containing descriptive information should be submitted protected (e.g., in a sleeve, jewel case, physical media mailer) to the FDA. The protected physical medium should be attached securely to a jacket (e.g., notebook,

[10] The FDA is in the process of developing a system for accepting files in Portable Document Format (PDF) through the EDI gateway and plans to have this capability in the near future.

[11] Ibid.

[12] Expedited ICSRs and/or ICSR attachments should be submitted to the FDA on a separate physical medium as described in the *Expedited Safety Reports Guidance of* 2001.

binder). This physical medium should not contain any ICSRs and/or ICSR attachments.

A jacket can contain more than one unit of physical medium. Each unit of the physical media should be securely attached to the jacket and should have included on its label, in addition to other identifying information (see sections III.C and IV in this guidance), the media series (e.g., "1 of 2," "2 of 2"). If more than one unit of physical medium is contained in the jacket, the label on the jacket should include, in addition to other identifying information (see section III.C and IV in this guidance), the number of units of physical media in the jacket (e.g., "Jacket contains 2 CD ROMS").

These physical media should be sent to the FDA at the following address[13]:

Central Document Room
Attn: AERS
Food and Drug Administration
12229 Wilkins Avenue
Rockville, MD 20852

4. Submission Date

As described in our current regulations, ICSRs, ICSR attachments, and descriptive information for a postmarketing periodic adverse experience report must be submitted to the FDA within 30 days of the close of the quarter for postmarketing periodic adverse experience reports due quarterly and within 60 days of the anniversary date of approval of the application for postmarketing periodic adverse experience reports due annually (see 21 CFR 314.80(c)(2)(i) and 600.80(c)(2)(i)).

E. Notification of Receipt of Report by the FDA

1. ICSR sent to the EDI gateway

Once an ICSR reaches the EDI gateway and is successfully recognized and decrypted, an EDI gateway acknowledgement will be returned to the sender. The date of this acknowledgement will serve as the official FDA receipt date of the ICSR.

After receipt of the ICSR, we will load it into the AERS database. For ICSRs sent via the EDI gateway, an automated standard generalized markup language (SGML) acknowledgment message, which gives the status of each ICSR in the transmission, will be returned to you via the gateway.

[13] Descriptive information that is submitted to the FDA on paper instead of in an electronic format must continue to be submitted as described under 21 CFR 314.80(c) and 600.80(c).

We expect that you will receive your EDI gateway and SGML acknowledgements within 24 hours after you have submitted an ICSR to the EDI gateway. If you do not receive these acknowledgements within 24 hours, you should first check our Web site on the Internet at www.fda.gov/oc/electronicsubmissions/interfaq.htm to see if we are experiencing any problems with the EDI gateway and/or AERS. If both the EDI gateway and AERS are functional, you should contact the AERS electronic submission coordinator at aersesub@cder.fda.gov to determine why you have not received your acknowledgements.

If the EDI gateway is not functional and you decide to meet your regulatory requirements by submitting your ICSRs on physical media, you should not resubmit the ICSRs to us using the EDI gateway when it becomes functional. In this case, the official FDA receipt date of the ICSRs is the date the physical media arrives at the Agency.

If the EDI gateway is functional, but AERS is not functional, you should not submit your ICSRs to us by other means (i.e., physical media or paper). We will load your ICSRs into AERS as soon as AERS is functional. At that time, you will receive an SGML acknowledgement. If the EDI gateway or AERs is not functional, a resubmission could affect FDA receipt dates. When appropriate, we will work with you to reset the receipt date, and you should keep relevant documentation for compliance purposes.

If your ICSR is received by the EDI gateway, but we are not able to load it into the AERS database because you have not submitted it in accordance with the ICH recommendations described in the *Expedited Safety Reports* guidance, the SGML acknowledgement that you receive will indicate that we could not load this ICSR into AERS. Other ICSRs that you send to the EDI gateway at the same time that we are able to load into AERS would also be indicated in the SGML acknowledgement. You should only resubmit to us those ICSRs that were not loaded into AERS. This resubmission should take place as soon as possible. The date of the EDI gateway acknowledgement for the resubmission will serve as the official FDA receipt date of the ICSR. If you are not able to correct and resubmit your ICSR in an electronic format in a timely manner you should submit it to the FDA by other means (e.g., on paper) to meet your regulatory requirements.[14]

2. Periodic adverse experience reports sent on physical media

For submissions sent on physical media, the Agency will determine the receipt date as it does with submissions sent to the FDA on paper (i.e., receipt date is the date it arrives at the Agency). The Agency will only contact you if there are problems with the format of the report or if the report does not load properly into our systems. We will contact you by phone or email within 3 working days after

[14] See 21 CFR 314.80(c)(2(ii)(b) and 600.80(c)(2)(ii)(B).

we receive your report, describe the problem, and request a resubmission of the report in the proper format.[15] This resubmission should take place as soon as possible. The receipt date of the resubmission will serve as the official receipt date of the report. If you are not able to resubmit your report in an electronic format in a timely manner you should submit it to the FDA by other means (e.g., on paper) to meet your regulatory requirements.[16]

As already mentioned, if the EDI gateway or AERs is not functional, a resubmission could affect FDA receipt dates. When appropriate, we will work with you to reset the receipt date, and you should keep relevant documentation for compliance purposes.

If your ICSR is submitted to us using the EDI gateway and your ICSR attachments and descriptive information are submitted to us on separate physical media, the EDI gateway acknowledgement for the ICSR will serve as the official FDA receipt date of the ICSR; the date that we receive the physical medium containing the ICSR attachments will serve as the official FDA receipt date of the ICSR attachments and the date that we receive the physical medium containing the descriptive information will serve as the official FDA receipt date of the descriptive information. Even though these ICSRs, ICSR attachments and descriptive information may be received by the FDA on different days, they are all required, as noted above, to be submitted to the Agency within 30 days of the close of the quarter for postmarketing periodic adverse experience reports due quarterly and within 60 days of the anniversary date of approval of the application for postmarketing periodic adverse experience reports due annually (see 21 CFR 314.80(c)(2)(i) and 600.80(c)(2)(i)). Please plan your submissions accordingly.

III. ORGANIZING THE ELECTRONIC SUBMISSION

A. Periodic ICSRs and ICSR attachments

You should organize the periodic ICSRs and ICSR attachments as described in the *Expedited Safety Reports* guidance. The following additional information is provided to assist applicants.

For E2B/E2BM field, A.1.9 “Does this case fulfill the local criteria for an expedited report?” the field value should be “2” for the response “No.” This response will indicate to the FDA that the ICSR is for a postmarketing periodic adverse drug experience report.

[15] The FDA intends to contact applicants within 24 hours after receipt of an expedited ICSR or ICSR attachment on physical media if there is a problem with the format of the ICSR or ICSR attachment.

[16] See 21 CFR 314.80(c)(2) and 600.80(c)(2).

For the E2B field, B.2.i.1 "Reaction/event as reported by the primary source," you should insert the original reporter's words and/or short phrases used to describe the reaction/event. For the E2B field B.2.i.2 "Reaction/event term," the FDA prefers that applicants use the preferred term (PT) from the Medical Dictionary for Regulatory Activities (MedDRA)[17] that most closely corresponds to the term reported by the original reporter. If you wish to include the lowest level term (LLT) in MedDRA that most closely corresponds to the term reported by the original reporter, you should insert this term in the E2B field B.2.i.1. MedDRA terms should be provided as codes. If you do not have access to MedDRA, you should populate the E2B field B.2.i.1 with the original reporter's words and/or short phrases used to describe the reaction/event and populate the E2B field B.2.i.2 with a reaction term from a standardized dictionary (e.g., a COSTART term, a WHOART term).

For the E2BM field, B.2 "Reaction(s)/event(s)," the FDA prefers that applicants use terms in MedDRA. For the E2BM field B.2.i.0 "Reaction/event as reported by the primary source," you should insert the original reporter's words and/or short phrases used to describe the reaction/event. For the E2BM field B.2.i.2 "Reaction/event MedDRA term (Preferred Term)," you should insert the PT in MedDRA that most closely corresponds to the term reported by the original reporter. If you wish to include in your ICSR the LLT in MedDRA that most closely corresponds to the term reported by the original reporter, you should insert this term in the E2BM field B.2.i.1. "Reaction/event in MedDRA terminology (Lowest Level Term)." As noted above, MedDRA terms should be provided as code. If you do not have access to MedDRA, you should populate the E2BM field B.2.i.2 with a reaction term from a standardized dictionary (e.g., a COSTART term, a WHOART term) and leave the E2BM field B.2.i.1 blank.

For E2B/E2BM field B.4.k.4.1 "Authorization/Application Number," the following format should be used.[18] For human drug products, the abbreviation "NDA" or "ANDA" should be followed by a space and then the number for the application (e.g., NDA 12345, ANDA 12345). For human biological products, the six digit submission tracking number (STN) (e.g., 123456), which is the BLA number, should be used for this purpose. The same format as described for human drug products should be used (e.g., STN 123456).

The E2B/E2BM field, B.5.1 "Case narrative including clinical course, therapeutic measures, outcome and additional relevant information" should contain data for your ICSR to be loaded into AERS. The narrative description of the adverse drug experience should be provided in this field and not included in any other E2B/E2BM field. If the information that you have for this field (or any other E2B/E2BM field) exceeds the maximum allowable length for the field, you should consider alternative ways to convey

[17] Companies can license MedDRA from an international maintenance and support services organization (MSSO) (toll free number 877-258-8280 (703-345-7799 in Washington, D.C. area), fax 703-345-7755, e-mail subscrib@meddramsso.com, Internet at www.meddramsso.com).

[18] Please note that as the ICSR from an applicant is a regulatory submission, B.4.k.4.1 should be populated to document the approved application to which the applicant is filing the report (ICSR).

the information so that it will fit (e.g., use abbreviations, describe the information using fewer words).

Followup reports should provide a complete picture of the current understanding of an adverse experience, rather than providing only the changes and/or updates to an ICSR. For information on the content and reporting considerations for followup reports to ICSRs submitted to the Agency, see the guidance for industry entitled *Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines*.[19] The information in the March 2001 draft guidance applies to electronic submission of followup reports except that rather than highlighting (e.g., with an asterisk, underline) in the followup report new information or correction of previously submitted inaccurate information, you should make a note of this information in the narrative section of the followup report (E2B/E2BM field B.5.1). The identification numbers (E2B/E2BM fields in section A.1) used in followup reports should remain unchanged from those included in the initial ICSR. Thus, the initial ICSR and all of its followup reports will be linked in AERS. For example, if your initial ICSR is submitted to the FDA on paper with its manufacturer control number as its identification number and you wish to submit followup reports for the ICSR in an electronic format, you should use the manufacturer control number from the initial ICSR report as your identification number for all of the followup reports. Accordingly, if your initial ICSR is submitted to the FDA in an electronic format with a concatenation of the country code, sender identification, and report number as its identification number and you wish to submit a followup report for the ICSR on paper, you should use the concatenated number from the initial ICSR report as your identification number for the followup report. Once an identification number field is populated, you should not change the information contained in it for any subsequent followup reports. If your firm reassigns identification numbers to internal files for submitted ICSRs (e.g., if you consolidate duplicate reports, change data handling procedures, or assume reporting responsibility for previously marketed products), you should not use the reassigned internal identification number in E2B/E2BM fields in section A.1 of the followup reports. Because we track followup reports with the original reports, you should continue to use the original identification number in the E2B/E2BM fields in section A.1 of the followup reports, but you can note the reassigned internal identification number in the narrative section of the followup report (E2B/E2BM field B.5.1) (e.g., "This event has been reassigned Company A ID number COA12345"). If you inadvertently use an incorrect identification number in a followup report, you should contact the AERS electronic submission coordinator at aersesub@cder.fda.gov to determine how to correct the mistake.

B. Descriptive Information

You should supply the descriptive information in a file named *descriptiveinfo.pdf* using Portable Document Format (PDF). You should provide bookmarks to each of the sections and subsections of this report. The *descriptiveinfo.pdf* file should be placed within a

[19] A draft version of the Postmarketing guidance was issued in March 2001. Once finalized it will represent the Agency's current thinking on followup reports.

folder on the physical medium named with the NDA, ANDA, or STN number for the product (e.g., NDA 12345, ANDA 12345, STN 123456).

C. Physical media

1. Periodic ICSRs/ICSR attachments for human drug and biological products

You can send periodic ICSRs and ICSR attachments for human drug and biological products on the same physical medium (e.g., on a single CD-ROM). See Table 1. This physical medium and its jacket should be labeled with the following information (i.e., on the medium and jacket so that is can be visualized immediately):

1. "Periodic ICSRs - Postmarketing Safety Report Submission"
2. Company name
3. Name, phone number, and email address of person at the company that we can contact if any problems arise with processing the physical medium at the FDA.
4. For human drug products, include the abbreviation CDER and the NDA and/or ANDA number(s), as appropriate, for the product (e.g., "CDER/NDA 12345," "CDER/ANDA 12345," "CDER/NDA 12345/NDA 78910"). For human biological products, include the abbreviation CBER and the STN number for the product (e.g., "CBER/STN 123456").

All ICSRs on the physical medium should be placed within a folder on the physical medium named *Periodic ICSRs*. All ICSR attachments on the physical medium should be placed within a folder on the physical medium named *Periodic ICSR attachments.* Descriptive information for a postmarketing periodic safety report should not be included on a physical medium that contains periodic ICSRs and/or ICSR attachments.

2. Descriptive information for human drug and biological products

You should only include descriptive information (i.e., *descriptiveinfo.pdf* file) for one NDA, ANDA, or BLA on each physical medium (see Table 1). This physical medium and its jacket should be labeled with the following information (i.e., on the medium and jacket so that is can be visualized immediately):

1. "Descriptive Information – Postmarketing Periodic Safety Report Submission"
2. Company name
3. Name, phone number, and email address of person at the company that we can contact if any problems arise with processing the physical medium at the FDA.
4. For human drug products, include the abbreviation CDER and the NDA or ANDA number, as appropriate, for the product (e.g., "CDER/NDA 12345," "CDER/ANDA 12345"). For human biological products, include the abbreviation CBER and the STN number for the product (e.g., "CBER/STN 123456").

ICSRs and ICSR attachments should not be included on a physical medium that contains descriptive information for a postmarketing periodic safety report.

Table 1: Submission of Postmarketing Periodic Safety Reports on Physical Media[20]

Safety Report	Report included on physical medium labeled "Periodic ICSRs – Postmarketing Safety Report Submission?"	Report included on physical medium labeled "Descriptive Information – Postmarketing Periodic Safety Report Submission?"	Which folder on the physical medium should report be contained in?	What file name should be used for report?	What extension should be used for the file name?
Periodic ICSRs	Yes[21]	No	*Periodic ICSRs*	Any file name with 40 or less characters	*edi*
Periodic ICSR attachments	Yes[22]	No	*Periodic ICSR attachments*	Any file name except the name *descriptiveinfo*	*pdf*
Descriptive information for NDA, ANDA, or BLA	No	Yes[23]	Folder named with NDA, ANDA or STN number for the product	*descriptiveinfo*	*pdf*

IV. PERIODIC SAFETY UPDATE REPORTS (PSUR)

Under 21 CFR 314.90(a) and 600.90(a), you can request a waiver of the requirement to submit postmarketing periodic adverse experience reports.[24] Instead, you can prepare these reports using the PSUR format described in the guidance for industry *E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs*. If you choose to submit your PSUR in an electronic format, you should provide the report as a single PDF file named *descriptiveinfo.pdf*. You should provide bookmarks for the table of contents of the PSUR.

[20] For guidance on submitting postmarketing expedited safety reports, 15-day Alert reports, on physical media see *Expedited Safety Reports* guidance.

[21] Do not include expedited ICSRs on this physical medium.

[22] Do not include expedited ICSR attachments on this physical medium.

[23] Only include descriptive information for one NDA, ANDA, or BLA on each physical medium.

[24] The process for submitting a waiver is explained in the guidance for industry *Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines*, which was issued as a draft in March 2001. Once finalized that guidance will represent the Agency's thinking on submitting a waiver.

You should place the PDF file, *descriptiveinfo.pdf*, within a folder on the physical medium using the NDA, ANDA, or STN number (e.g., NDA 12345, ANDA 12345, STN 123456) as the folder name. You should include one PSUR on a physical medium unless the PSUR contains information for more than one NDA or ANDA. In this case, a separate folder on the physical medium should be provided for each NDA or ANDA using its application number as the folder name. Each of these folders should contain the same *descriptiveinfo.pdf* file for the PSUR. All of these folders (i.e., for the same PSUR) may be included on a single physical medium.

The physical medium and its jacket should be labeled with the following information:

1. "Descriptive Information – Postmarketing Periodic Safety Report Submission"
2. Company name
3. Name, phone number, and email address of person at the company that we can contact if any problems arise with processing the physical medium at the FDA.
4. For human drug products, include the abbreviation CDER and the NDA and/or ANDA number(s), as appropriate, for the product (e.g., "CDER/NDA 12345," "CDER/ANDA 12345," "CDER/NDA 12345/NDA 78910"). For human biological products, include the abbreviation CBER and the STN number for the product (e.g., "CBER/STN 123456").

In addition to the format of the PSUR described in E2C, you must submit to the FDA periodic ICSRs that are required by the regulations (see 21 CFR 314.80(c)(2)(ii)(b) and 600.80(c)(2)(ii)(B)). These periodic ICSRs can be provided to the Agency in an electronic format as described in sections II.D.1, II.D.3, II.D.4, II.E, III.A and III.C.1 of this guidance.