FDA eSubmitter Screen Shots for eMDR

OMB Control No. 0910-xxxx
Expiration Date xx / xx /xxxx

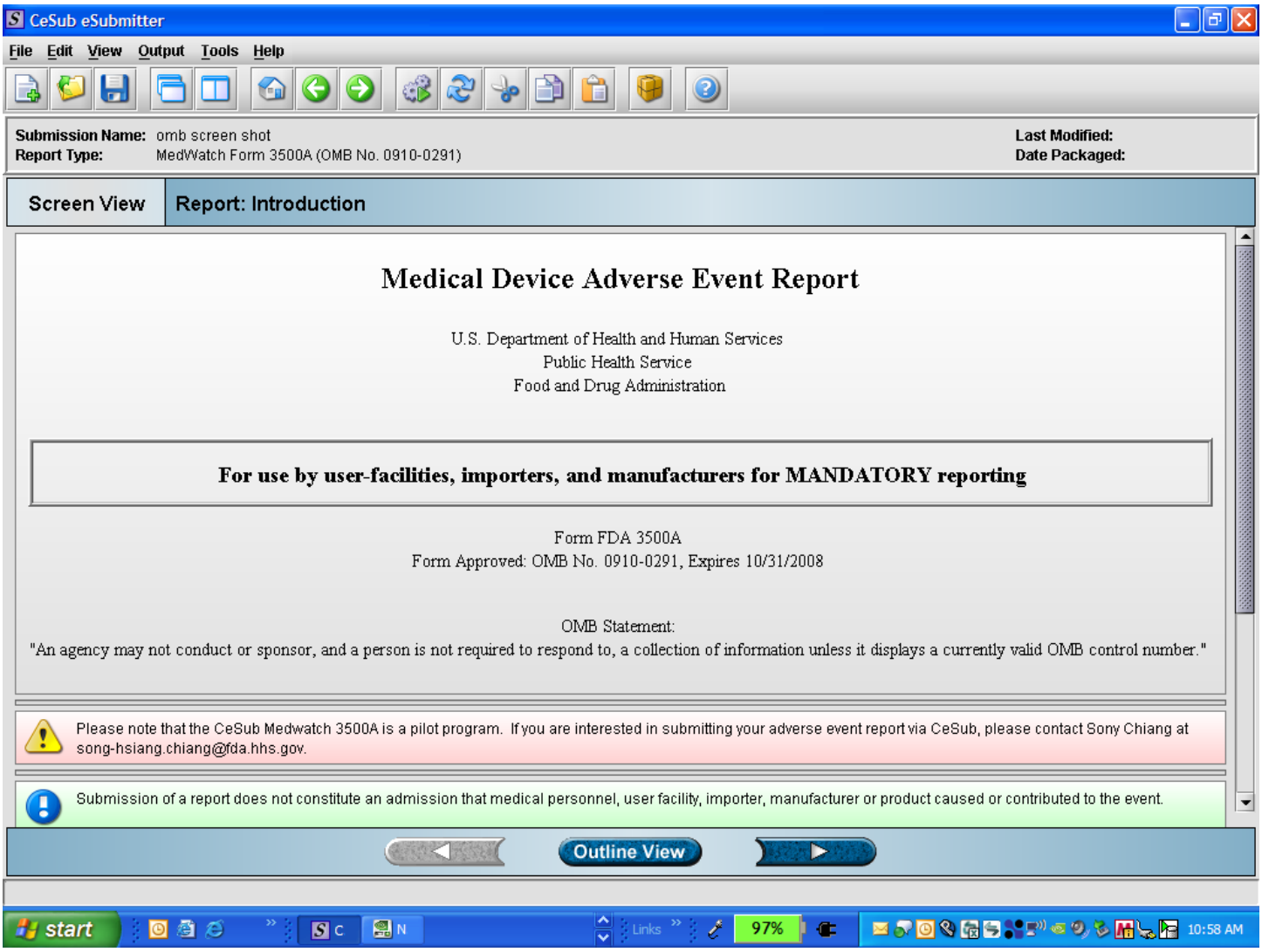
The public reporting burden for this collection of information has been estimated to average 9 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

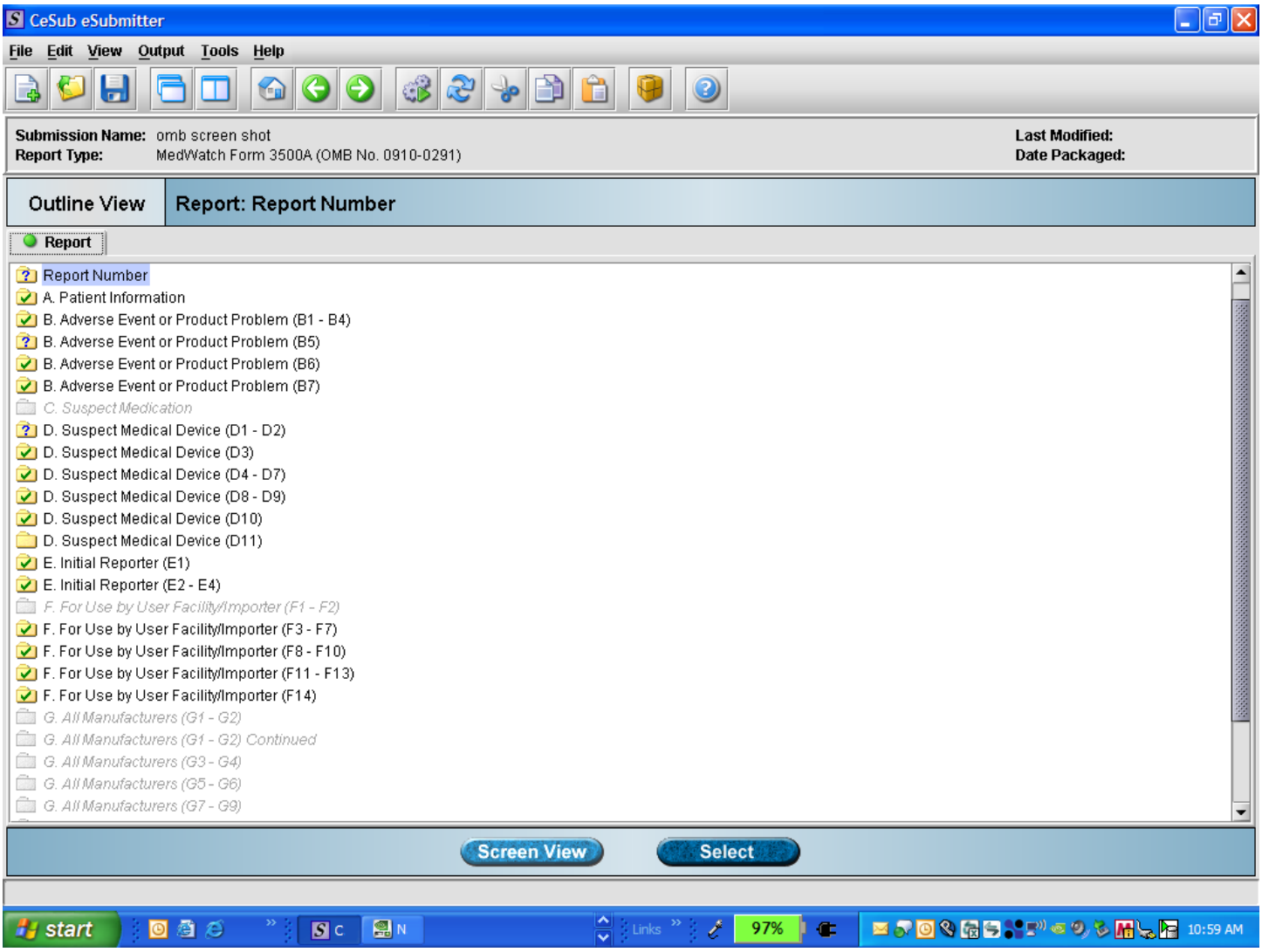
Department of Health and Human Services
Food and Drug Administration
MedWatch HFD-410
5600 Fishers Lane
Rockville, MD 20857

Please DO NOT RETURN this form to this address.

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 control number.


CeSub eSubmitter
File Edit View Output Tools Help
Submission Name: omb screen shot
Report Type: MedWatch Form 3500A (OMB No. 0910-0291)
Last Modified:
Date Packaged:
Screen View
Report: Introduction
Medical Device Adverse Event Report
U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
For use by user-facilities, importers, and manufacturers for MANDATORY reporting
Form FDA 3500A
Form Approved: OMB No. 0910-0291, Expires 10/31/2008
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 control number."
Please note that the CeSub Medwatch 3500A is a pilot program. If you are interested in submitting your adverse event report via CeSub, please contact Sony Chiang at song-hsiang.chiang@fda.hhs.gov.
Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.
Outline View
start
97%
10:58 AM


CeSub eSubmitter
File Edit View Output Tools Help
Submission Name: omb screen shot
Report Type: MedWatch Form 3500A (OMB No. 0910-0291)
Last Modified:
Date Packaged:
Outline View
Report: Report Number
Report
Report Number
A. Patient Information
B. Adverse Event or Product Problem (B1 - B4)
B. Adverse Event or Product Problem (B5)
B. Adverse Event or Product Problem (B6)
B. Adverse Event or Product Problem (B7)
C. Suspect Medication
D. Suspect Medical Device (D1 - D2)
D. Suspect Medical Device (D3)
D. Suspect Medical Device (D4 - D7)
D. Suspect Medical Device (D8 - D9)
D. Suspect Medical Device (D10)
D. Suspect Medical Device (D11)
E. Initial Reporter (E1)
E. Initial Reporter (E2 - E4)
F. For Use by User Facility/Importer (F1 - F2)
F. For Use by User Facility/Importer (F3 - F7)
F. For Use by User Facility/Importer (F8 - F10)
F. For Use by User Facility/Importer (F11 - F13)
F. For Use by User Facility/Importer (F14)
G. All Manufacturers (G1 - G2)
G. All Manufacturers (G1 - G2) Continued
G. All Manufacturers (G3 - G4)
G. All Manufacturers (G5 - G6)
G. All Manufacturers (G7 - G9)
Screen View
Select
start
Links
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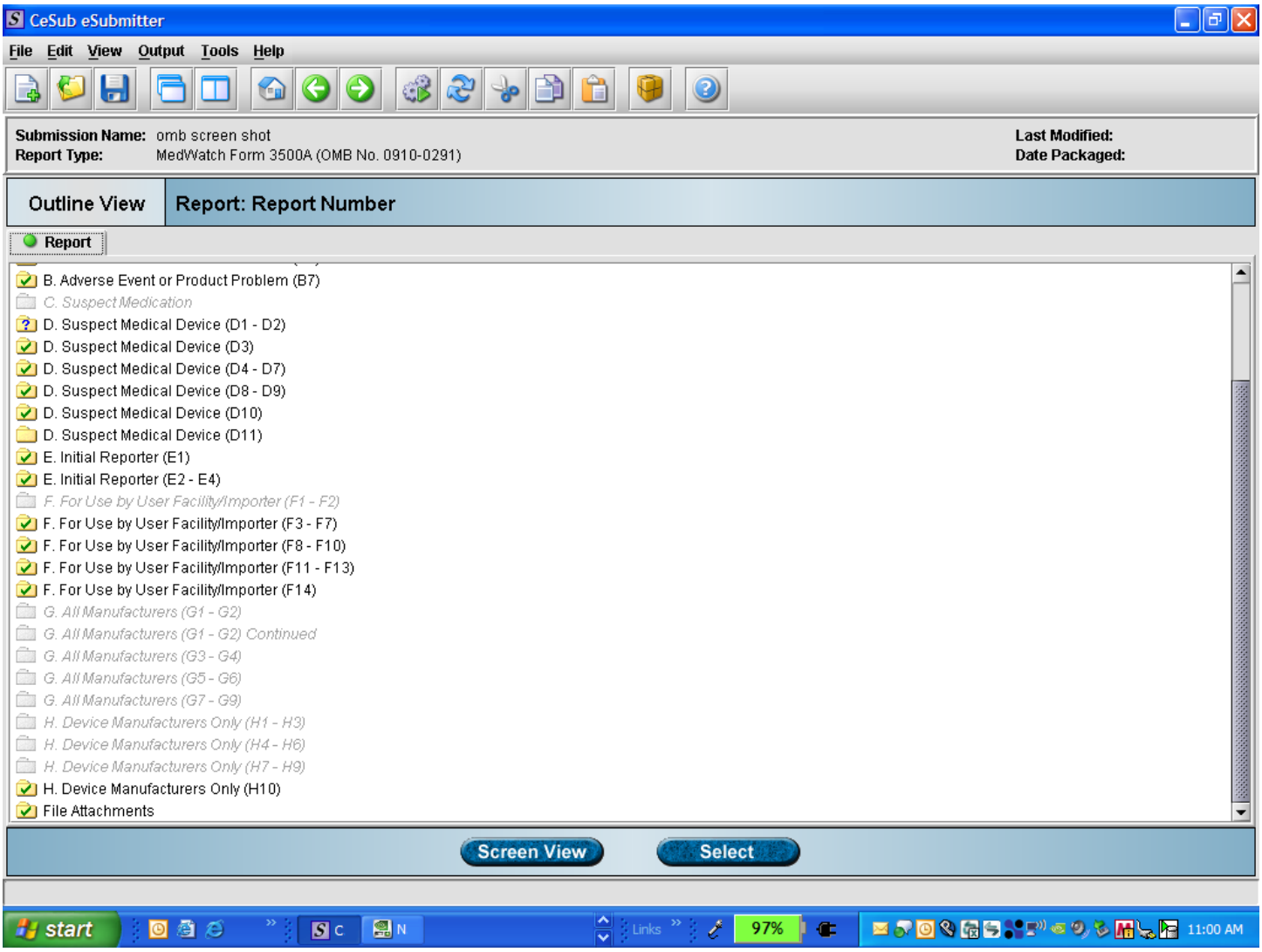
10:59 AM


CeSub eSubmitter
File Edit View Output Tools Help
Submission Name: omb screen shot
Report Type: MedWatch Form 3500A (OMB No. 0910-0291)
Last Modified:
Date Packaged:
Outline View
Report: Report Number
Report
B. Adverse Event or Product Problem (B7)
C. Suspect Medication
D. Suspect Medical Device (D1 - D2)
D. Suspect Medical Device (D3)
D. Suspect Medical Device (D4 - D7)
D. Suspect Medical Device (D8 - D9)
D. Suspect Medical Device (D10)
D. Suspect Medical Device (D11)
E. Initial Reporter (E1)
E. Initial Reporter (E2 - E4)
F. For Use by User Facility/Importer (F1 - F2)
F. For Use by User Facility/Importer (F3 - F7)
F. For Use by User Facility/Importer (F8 - F10)
F. For Use by User Facility/Importer (F11 - F13)
F. For Use by User Facility/Importer (F14)
G. All Manufacturers (G1 - G2)
G. All Manufacturers (G1 - G2) Continued
G. All Manufacturers (G3 - G4)
G. All Manufacturers (G5 - G6)
G. All Manufacturers (G7 - G9)
H. Device Manufacturers Only (H1 - H3)
H. Device Manufacturers Only (H4 - H6)
H. Device Manufacturers Only (H7 - H9)
H. Device Manufacturers Only (H10)
File Attachments
Screen View
Select
start
Links
97%
11:00 AM