Using Data Extracted from the AERS (Adverse Event Report System)

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A. Introduction

The accompanying disk contains an Access database containing records from the Adverse Event Reporting System (AERS) supplied to FOI Services by the government. The data included in this extract cover records received by the U.S. Food and Drug Administration (FDA) through June 30, 2009.

Based on the drug names (trade and/or generic) you provided, we searched for reports where any of the drug names specified were included in any portion of the drug name field. This method generally captures most instances of the selected drug, but may not recover records with spelling or typographical errors.

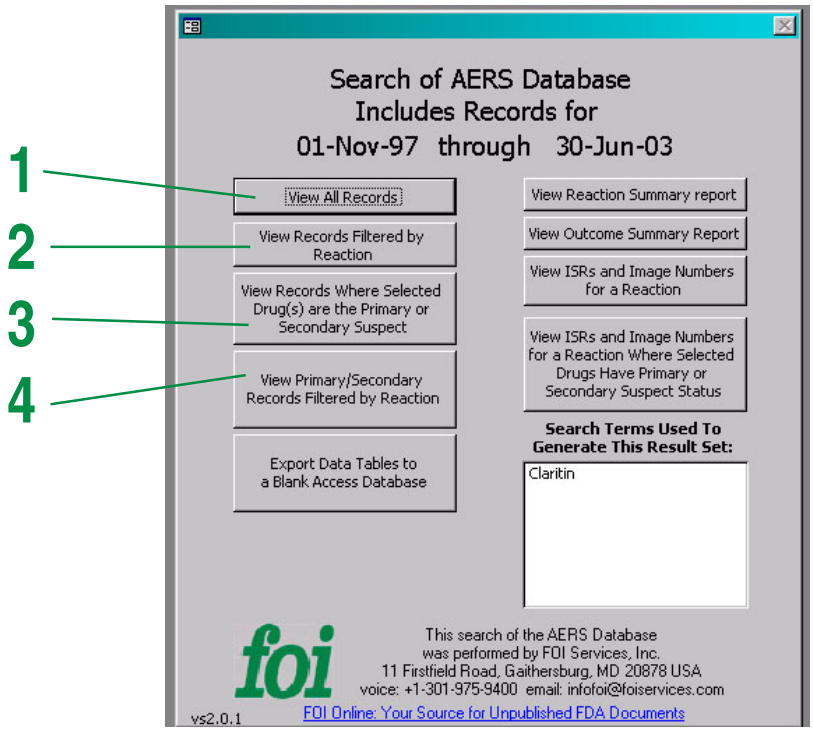
B. Installation Instructions

You must have Microsoft Access 2000 or higher version to view your results.

To view the results of your search, copy the [*drug name-AERS*.mdb] file on the CD to your hard drive (The file will not run directly from the CD). After copying, right click on the file name, select **Properties** from the menu tree and remove the check mark next to read only. Click the **OK** button to close the dialog box then double click on the file name. The Main Menu Form will display.

C. Record Viewing Options: The Main Menu Form

Records can be viewed as a complete set or filtered with the following options available from the buttons on the Main Menu Form:



1 — View All Records

All available information for each record (Individual Safety Report, or ISR) will display, sorted in descending chronological FDA date order. Each drug searched will be displayed, regardless of its status as a primary, secondary, or concomitant drug.

2 — View Records Filtered By Reaction

When you click this option, you will be asked to select available reactions from a drop down box. Only those ISRs containing that reaction will be displayed; drug(s) may be primary, secondary, or concomitant.

3 — View Records Where the Drug(s) searched are the Primary or Secondary Suspect

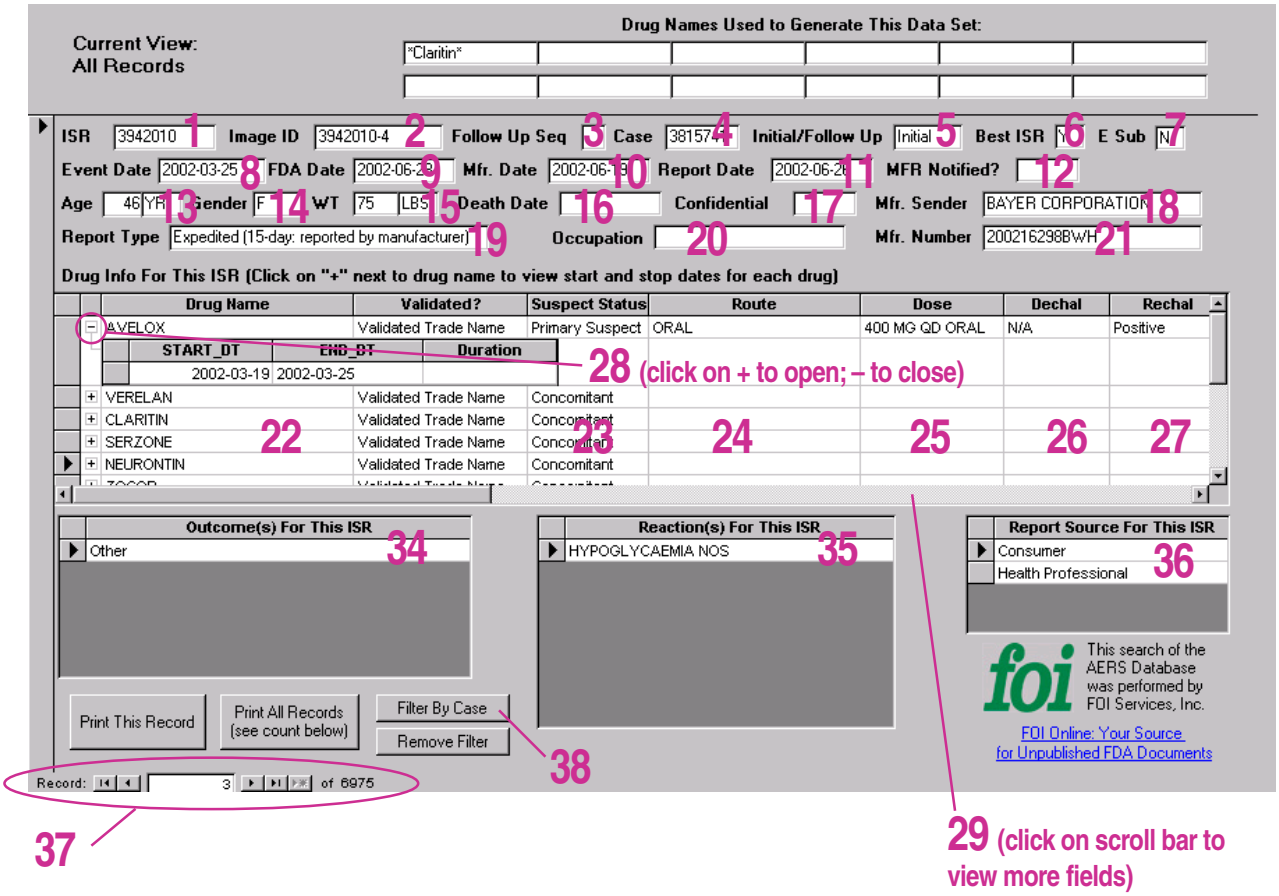
Records displayed will only include those where the drug name(s) used to generate the result set have primary or secondary suspect status.

4 — View Primary/Secondary Records Filtered by Reaction

Records displayed will be primary or secondary suspect drugs with the selected reaction.

D. Data Field Descriptions

Each report may contain the following information:



Data Fields in the Header Area:

1 — ISR (Individual Safety Report)

Unique number for identifying an AERS report (e.g: 3123456). *(See Note 1 in Section G)*

2 — Image ID

Identifier for an AERS report image. Character field consisting of the ISR number, a dash, and a check digit or letter (e.g: 3123456-X). *(See Note 3 in Section G)*

3 — Follow Up Seq

The sequence number of a follow-up report, as reported by manufacturer. For initial reports, there will be no data for this field (A small number of reports may have "bad" data for this number, such as alphabetic or special characters). *(See Note 2 in Section G)*

4 — Case

Number for identifying an AERS case. *(See Note 1 in Section G)* A case consists of one or more reports (ISRs). A follow-up report will have the same Case number as the initial report. *(See Note 2 in Section G)*

5 — Initial/Follow Up*
Initial or follow-up status of report, as reported by manufacturer. *(See Note 2 in Section G)*

6 — Best_ISR*
A Yes/No field indicating if this is the "best" (i.e. most recent) report received for this case.

7 — E_Sub*
Yes/No field indicating if this report was submitted under the electronic submissions procedure for manufacturers.

8 — Event Date
Date adverse event occurred or began. (YYYY-MM-DD format)

9 — FDA Date
Date FDA received report. (YYYY-MM-DD format)

10 — Mfr. Date
Date manufacturer first received initial (or follow-up) information. (YYYY-MM-DD format)

11 — Report Date*
Date report was sent to FDA.

12 — MFR Notified?*
Yes/No field indicating if the voluntary reporter also notified the manufacturer.

13 — Age
Numeric value of patient's age at event, followed by code indicating units of age measurement:
DEC=Decades YR= Years MON=Months WK=Weeks DY=Days HR=Hours

14 — Gender
Code for patient's sex:
M=Male F=Female UNK=Unknown NS=Not Specified

15 — Weight*
Numeric value of patient's weight, followed by the unit of measurement:
KG=Kilograms LBS=Pounds GMS=Grams

16 — Death Date*
Date patient died. (YYYY-MM-DD format)

17 — Confidential*
Yes/No field indicating if the voluntary reporter's identity can be disclosed to the manufacturer.

18 — Mfr. Sender
Verbatim name of manufacturer sending report. *(See Note 5 in Section G)*

19 — Report Type
Type of report submitted:
Expedited (15-day; reported by manufacturer)
Periodic (reported by manufacturer)
Direct (reported by non-manufacturer) *(See Note 4 in Section G)*

**These fields appear only in records added in the June 30, 2002 quarterly update to the data or later.*

20 — Occupation*
Initial reporter's type of occupation.

21 — Mfr. Number
Manufacturer's unique report identifier.

Drug Section Information

22 — Drug Name
Name of medicinal product. If a valid trade name is listed it will be followed by "Validated Trade Name" in the "Validated?" column. If the drug name has not been validated, but entered exactly as it was received in the report, it will be followed by "Verbatim Drug Name" in the "Validated?" column. For the majority of reports there is a valid trade name. *(See Note 5 in Section G)*

23 — Suspect Status
Indicates a drug's reported role in event:

Primary Suspect Drug
Secondary Suspect Drug
Concomitant
Interacting

24 — Route
Verbatim text for frequency and route, exactly as reported.

25 — Dose
Verbatim text for dosage as reported.

26 — Dechal
Dechallenge result, indicating if reaction abated when drug therapy was stopped:

Positive dechallenge
Negative dechallenge
Unknown
Does not apply

27 — Rechal
Rechallenge result, indicating if reaction recurred when drug therapy was restarted:

Positive rechallenge
Negative rechallenge
Unknown
Does not apply

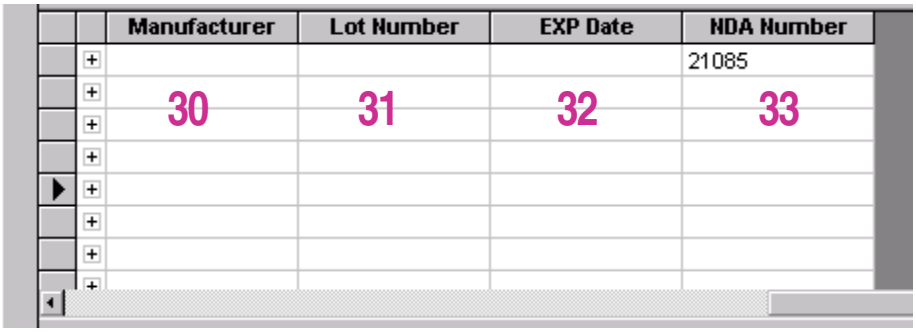
28 — Therapy Dates
(click on the + to the left of each drug name):

START_DT indicates the date therapy was started (or re-started) for this drug. (YYYY-MM-DD)
END_DT indicates the date therapy was stopped for this drug. (YYYY-MM-DD)
Duration provides the numeric value and unit for the duration (length) of therapy:

YR=Years	MON=Months	WK=Weeks	DAY=Days
HR=Hours	MIN=Minutes	SEC=Seconds	

**These fields appear only in records added in the June 30, 2002 quarterly update to the data or later.*

29 — Click on Right Scroll Bar for the Following Additional Fields:



30 — Manufacturer

Drug manufacturer as reported.

31 — Lot Number*

Lot number as reported.

32 — EXP Date*

Expiration date as reported (YYYY-MM-DD format).

33 — NDA Number*

New Drug Application number, if supplied.

Note: FOI Services has observed that NDA numbers are frequently incorrect in this field. Do not rely upon the accuracy of this field.

34 — Outcome(s) for This ISR

Possibilities are:

- Death
- Life-Threatening
- Hospitalization - Initial or Prolonged
- Disability
- Congenital Anomaly Required Intervention to Prevent Permanent Impairment/Damage
- Other

35 — Reaction(s) For This ISR

Lists the Preferred Term(s) level medical terminology describing the event, using the Medical Dictionary for Regulatory Activities (MedDRA). The order of the terms for a given event is alphabetical and does not imply priority.

36 — Report Source For This ISR

Indicates the source of the report. More than one may be indicated:

- Foreign
- Study
- Literature
- Consumer
- Health Professional
- User Facility
- Company Representative
- Distributor
- Other

**These fields appear only in records added in the June 30, 2002 quarterly update to the data or later.*

37 — Record Navigation Bar
Use the arrows in this bar to move between records.

38 — Filter By Case Button
This button displays all records relating to a particular case. This is useful for following up on a case from a previous AER database.

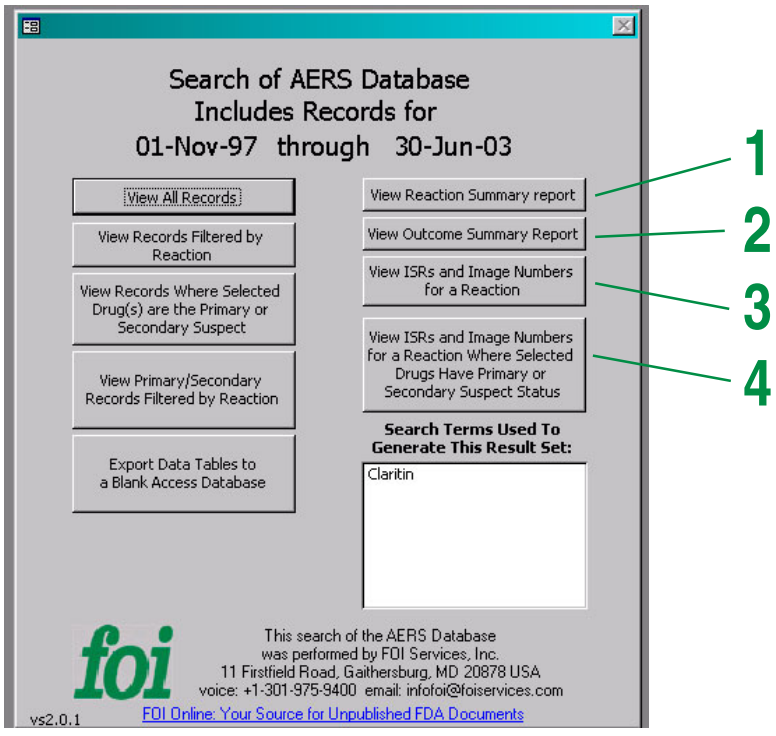
**These fields appear only in records added in the June 30, 2002 quarterly update to the data or later.*

E. Reports
Four reports can be generated from the Main Menu form.

Printing Information
All printing is sent to your default printer. To select another printer, right click on the report body or the record viewing screen and select page setup. On the page tab you will find a printer selection area.

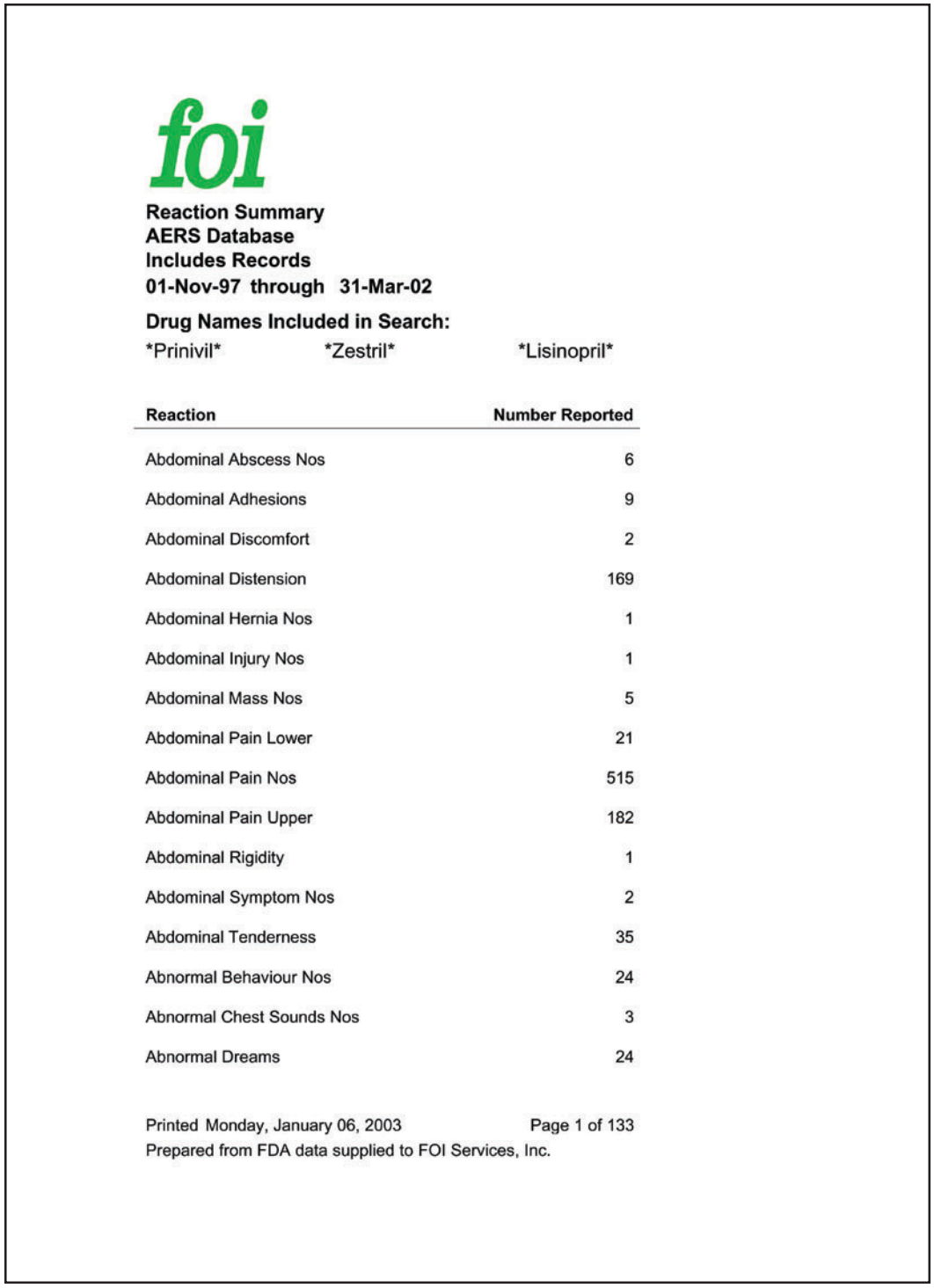
Additionally, on the record viewing screens there are buttons to print either the current record or all records in the current set.

It is suggested that the Print All Records button not be used unless the current result set is not large.



1 — View Reaction Summary Report

Clicking this button will list the number of instances of each reaction reported. The report is arranged alphabetically by reaction and indicates the dates and drug names covered.



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Reaction Summary
AERS Database
Includes Records
01-Nov-97 through 31-Mar-02

Drug Names Included in Search:
Prinivil *Zestril* *Lisinopril*

Reaction	Number Reported
Abdominal Abscess Nos	6
Abdominal Adhesions	9
Abdominal Discomfort	2
Abdominal Distension	169
Abdominal Hernia Nos	1
Abdominal Injury Nos	1
Abdominal Mass Nos	5
Abdominal Pain Lower	21
Abdominal Pain Nos	515
Abdominal Pain Upper	182
Abdominal Rigidity	1
Abdominal Symptom Nos	2
Abdominal Tenderness	35
Abnormal Behaviour Nos	24
Abnormal Chest Sounds Nos	3
Abnormal Dreams	24

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Prepared from FDA data supplied to FOI Services, Inc.

2 — View Outcome Summary Report

This report lists all the outcomes reported in the selected data and reports the number of instances for each outcome.

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Outcome Summary
AERS Database
Includes Records
01-Nov-97 through 30-Jun-03
Drug Names Included in Search:
Claritin

Outcome	Number Reported
Congenital Anomaly	58
Death	280
Disability	292
Hospitalization - Initial or Prolonged	1705
Life-Threatening	362
Other	4131
Required Intervention to Prevent Permanent Impairm	471

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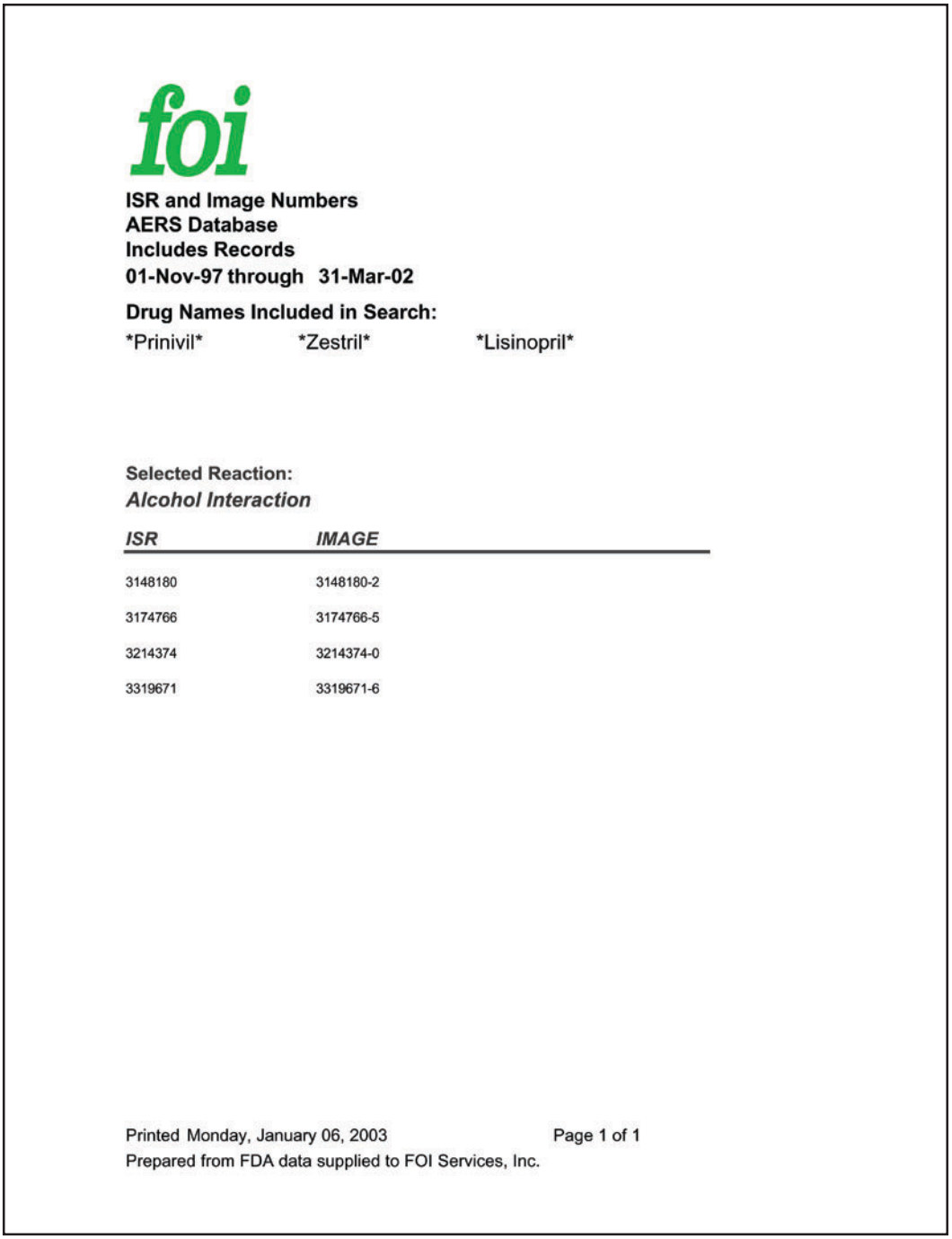
3 — ISR and Image Numbers for a Reaction Report

This report lists, in Image Number order, the ISRs and Image numbers for which a selected reaction is reported. This report is helpful primarily if you are contacting FDA about adverse reaction reports.



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ISR and Image Numbers
AERS Database
Includes Records
01-Nov-97 through 31-Mar-02

Drug Names Included in Search:
Prinivil *Zestril* *Lisinopril*

Selected Reaction:
Alcohol Interaction

ISR	*IMAGE*
3148180	3148180-2
3174766	3174766-5
3214374	3214374-0
3319671	3319671-6

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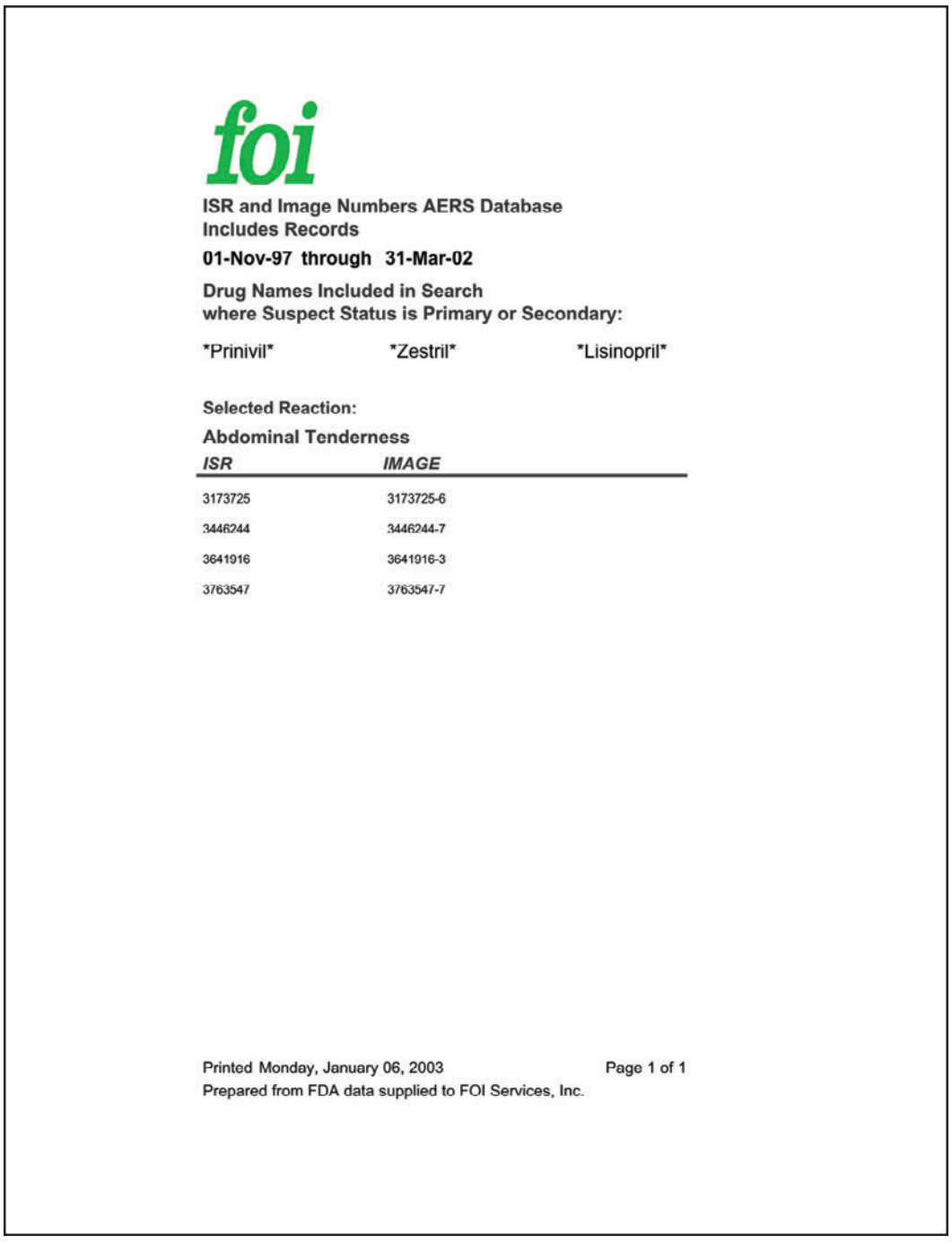
Prepared from FDA data supplied to FOI Services, Inc.

Note: FOI Services can obtain from FDA the Medwatch forms associated with the ISR and image numbers listed on this form. Call 301-975-9400 for more information.

4 — ISR and Image Numbers for a Reaction Where Selected Drugs Have Primary or Secondary Suspect Status Report

This report lists, in Image Number order, the ISRs and Image Numbers for which a selected reaction is reported and the drug names used to generate the data have primary or secondary suspect status.



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ISR and Image Numbers AERS Database
Includes Records

01-Nov-97 through 31-Mar-02

Drug Names Included in Search
where Suspect Status is Primary or Secondary:

Prinivil *Zestril* *Lisinopril*

Selected Reaction:

Abdominal Tenderness

ISR	IMAGE
3173725	3173725-6
3446244	3446244-7
3641916	3641916-3
3763547	3763547-7

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Prepared from FDA data supplied to FOI Services, Inc.

Note: FOI Services can obtain from FDA the Medwatch forms associated with the ISR and image numbers listed on this form. Call 301-975-9400 for more information.

F. Exporting the Data

In order to preserve the integrity of the data supplied to you we have hidden the underlying tables and database structure. However, if you would like to perform other analyses on these data we have included a button on the main menu which will export the data to a new database which you can manipulate yourself.

This feature will place seven tables containing the data from your search into a blank Access database. These tables are:

DEMOGRAPHIC contains a single record for each reported event with patient demographic and administrative information.

DRUG contains drug/biologic information for as many medications as were reported for the event (at least one, but often more, per event).

REACTION contains all Medical Dictionary for Regulatory Activities (MedDRA) terms coded for the adverse event (one or more per event). For more information on MedDRA, please contact: TRW, VAR1/8A/MSSO, 12011 Sunset Hills Road, Reston, VA 20190-3285, USA. Website is *www.meddramsso.com*

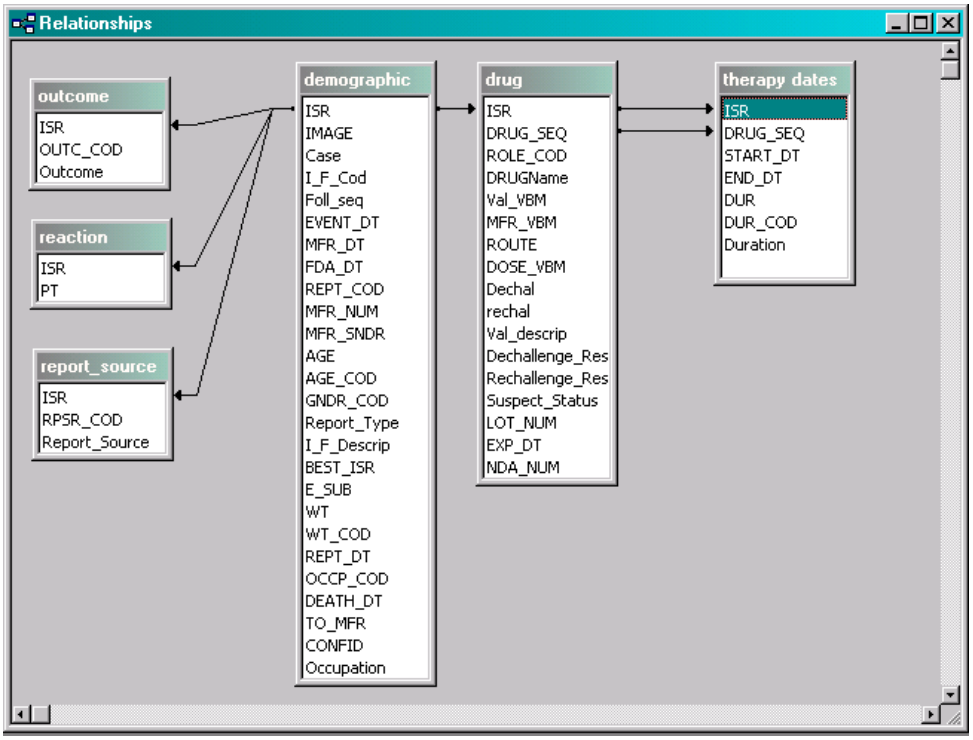
OUTCOME contains patient outcomes for the event (0 or more per event).

REPORT_SOURCE contains report sources for the event (0 or more per event).

THERAPY DATES contains drug therapy start dates and end dates for the reported drugs (0 or more per drug per event).

ORIGINAL SEARCH TERMS contains the drug names used to generate your result set.

The diagram below illustrates the relationships of the tables:



G. Data Notes from NTIS

Note 1: ISR (Demographic and other files). ISR numbers from 11/1/97 to the present will normally have a length of seven digits. However, because ISRs were initially planned to be 10 digits, almost 1,300 reports from November 1997 have 10-digit ISRs. There are about 300 CASE numbers with 10 digits, for the same reason.

Note 2: CASE, I_F_COD (**Initial/Follow Up** in this data set), and FOLL_SEQ (**Follow Up Seq** in this data set) (Demographic file). In AERS, a "case" consists of one or more reports (ISRs). If correctly linked, a followup report will have the same CASE number as the initial report (but a different ISR number). It should be kept in mind that the AERS system's determination of what is a follow-up will usually, but not always, agree with how a manufacturer shows follow-up status on a report. The I_F_COD code and the FOLL_SEQ number are basically verbatim data as given by the manufacturer; in contrast, the case number is based on the AERS system's independent determination of what it considers linked reports. For initial reports, there will be no FOLL_SEQ number.

Note 3: IMAGE (**Image ID** in this data set) (Demographic file). The Image number is the identifying number that should be used by anyone requesting sanitized hard copies of reports through the FOIA. Address: Food and Drug Administration, Freedom of Information Staff (HFI-35), 5600 Fishers Lane (Rm 12A-16), Rockville, MD, 20857, USA. Website: www.fda.gov/foi.

Note 4: REPT_COD (**Report Type** in this data set) (Demographic file). Expedited (15-day) and periodic reports are from manufacturers; "direct" reports are voluntarily submitted to the FDA by non-manufacturers.

Note 5: MFR_SNDR (Demographic file), DRUGNAME (Drug file), and possibly other fields. Because of a processing problem in handling the special characters ampersand ("&"), less-than ("<"), and greater-than (">"), it has been necessary to remove each such character, which has been replaced with a period (".") . (Example: MFR_SNDR "Merck Sharp & Dohme" becomes "Merck Sharp . Dohme".)

Note 6: DRUG_SEQ (Drug file and Therapy file) *(Note from FOI Services: the DRUG_SEQ number does not display in this data set).* The best way to explain the DRUG_SEQ (drug sequence number) is with an example. This will also serve to clarify the relationship between an ISR, the drug(s) reported for that ISR, and the therapy date(s) reported for the drug(s). Consider ISR 3078140, received by the FDA on 12/31/97. Like any ISR, it appears once (and only once) in the Demographic file:

ISR
3078140

Four drugs were reported for this ISR: Aricept was reported as suspect, and Estrogens, Prozac, and Synthroid as concomitant. ISR 3078140 appears four times in the Drug file, with a different DRUG_SEQ for each drug:

ISR	DRUG_SEQ	DRUG_VBM
3078140	1000157764	Aricept
3078140	1000589550	Estrogens
3078140	1000589552	Prozac (Fluoxetine Hydrochloride)
3078140	1000589553	Synthroid (Levothyroxine Sodium)

Dates of therapy for Aricept were reported as "4/97 to 6/13/97", and "6/20/97 (ongoing)". Since the drug was started, stopped, then restarted, there are two entries in the Drug Therapy file. In such a circumstance, the two entries will have the same ISR # and the same DRUG_SEQ # (see below). No therapy dates were reported for the concomitants; therefore, they do not appear in the Drug Therapy file, which is excerpted as follows:

ISR	DRUG SEQ #	START DT	END DT
3078140	1000157764	19970401	19970613
3078140	1000157764	19970620	

Another important thing to understand is that the association between a particular DRUG and a particular DRUG_SEQ # applies only for a particular ISR. For example, for ISR 3078140 Aricept just by chance received DRUG_SEQ # 1000157764; should it be reported for other ISRs, it would receive a different DRUG_SEQ # for each ISR.

For further information contact:

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