Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research

DSI COMPLAINT RECORD

Form Approved
OMB Control Number: 0910-0579
Expiration Date: March 31, 2009

See OMB Statement on Page 3.

- If you wish to report adverse events (adverse effects or adverse reactions) to drugs or report (medical) product problems, contact MEDWatch.
- If your complaint is about a research study, please complete this form.
- The purpose of this form is for collecting information about the potential scientific or research misconduct, or questionable research practices, involving the use of an FDA regulated drug product.
- You must answer the following two questions: (1) Who are you complaining about? and, (2) What is your complaint? If you do not know the answer to any other question in the complaint form, or if you do not wish to provide any additional information, you may leave a blank (unanswered) space following each question.

Who are you complaining about?

Please provide as much information as possible in this section. You must provide the name of a person, company, or organization about whom you are complaining. If you do not know the answer to any other question, or if you do not wish to provide any additional information, you may leave a blank (unanswered) space following each question.

Name of Person, Company, or Organization *(Required Information)*		Address		
Email Address *(If available)*		City	State or Province	ZIP / Postal Code
Telephone No. *(If available)*	Fax No. *(If available)*	Country		

What type of person or organization are you complaining about?

- ☐ Bioequivalence Facility
- ☐ Clinical Investigator (Study Physician)
- ☐ Clinical Study Site
- ☐ Contract Research Organization
- ☐ Institutional Review Board
- ☐ Monitor
- ☐ Nonclinical Laboratory
- ☐ Study coordinator
- ☐ Sponsor
- ☐ Other – Please specify: _____

Complaint Information

What is your complaint? *(Required Information)*

When did the event(s) take place? When did you participate in the study?

What is/are the name(s) of the study drug(s) or product(s), if known?

What is the type of drug or for what illness is it used? (For example, a drug to treat chest pains, seizures, depression, etc.)

What is/are the study(ies)? Include study title(s) or protocol number(s), if known?

If you know the name(s) of other persons (subjects or staff) who were involved in the study(ies), or anyone else who is willing to voluntarily provide information, please list them and include any available contact information (e.g., telephone number, fax number, email address, mailing address, etc.).

How many subjects were enrolled in the study(ies)?

Your Information (optional)

If you do not want FDA to know who you are, do not complete this section. FDA makes a good faith effort to protect the identities of complainants, but no assurance can be given to complainants that their identity will never be disclosed.

May the FDA contact you for more information?

- ☐ Yes
- ☐ No

How may we contact you? If by telephone, please suggest times that are convenient for you?

Please provide your contact information below.

Name		Address		
Email Address				
Telephone No.	Fax No.	City	State	ZIP Code

What is your affiliation with the study?

- ☐ Study Subject
- ☐ Sponsor
- ☐ Health Professional
- ☐ Ex-Employee
- ☐ FDA Staff
- ☐ University/Institution Staff
- ☐ Clinical Investigator
- ☐ Institutional Review Board
- ☐ Monitor
- ☐ Employee
- ☐ Media
- ☐ Other Government Employee
- ☐ Contract Research Organization
- ☐ Other – Please specify: _____

OMB Statement

Public reporting burden for this collection of information is estimated to average one hour 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 this 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
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

"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."