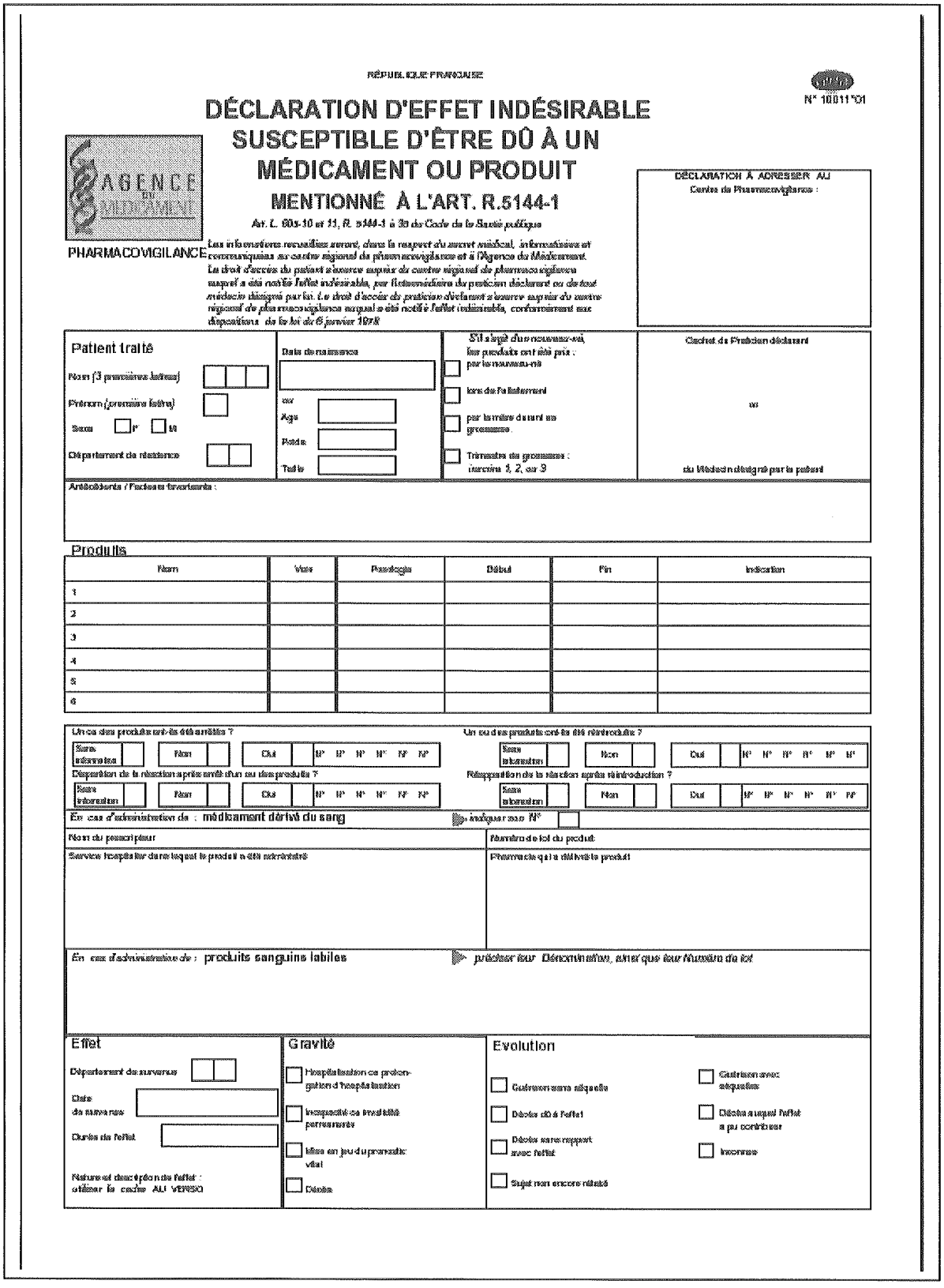
フランス　　副作用報告用紙（表）



RÉPUBLIQUE FRANÇAISE

N° 10811*01

DÉCLARATION D'EFFET INDÉSIRABLE SUSCEPTIBLE D'ÊTRE DÛ À UN MÉDICAMENT OU PRODUIT MENTIONNÉ À L'ART. R.5144-1

Art. L. 665-10 et 11, R. 5144-1 à 30 du Code de la Santé publique

AGENCE DU MÉDICAMENT

PHARMACOVIGILANCE

Les informations recueillies seront, dans le respect du secret médical, informatisées et communiquées au centre régional de pharmacovigilance et à l'Agence du Médicament. Le droit d'accès du patient s'exerce auprès du centre régional de pharmacovigilance auquel a été notifié l'effet indésirable, par l'intermédiaire du praticien déclarant ou de tout médecin désigné par lui. Le droit d'accès du praticien déclarant s'exerce auprès du centre régional de pharmacovigilance auquel a été notifié l'effet indésirable, conformément aux dispositions de la loi du 6 janvier 1978

DÉCLARATION À ADRESSER AU Centre de Pharmacovigilance :

Patient traité

Nom (3 premières lettres)

Prénom (première lettre)

Sexe ☐ F ☐ M

Département de résidence

Date de naissance

ou

Age

Poids

Taille

S'il s'agit d'un nouveau-né, les produits ont été pris :
☐ par le nouveau-né
☐ lors de l'allaitement
☐ par la mère durant sa grossesse.
☐ Trimestre de grossesse : (cocher 1, 2, ou 3)

Cachet du Praticien déclarant

ou

du Médecin désigné par le patient

Antécédents / Facteurs favorisants :

Produits

Nom	Voie	Posologie	Début	Fin	Indication
1					
2					
3					
4					
5					
6					

Un ou des produits ont-ils été arrêtés ? Sans information ☐ Non ☐ Oui ☐ N° N° N° N° N° N°

Un ou des produits ont-ils été réintroduits ? Sans information ☐ Non ☐ Oui ☐ N° N° N° N° N° N°

Disparition de la réaction après arrêt d'un ou des produits ? Sans information ☐ Non ☐ Oui ☐ N° N° N° N° N° N°

Réapparition de la réaction après réintroduction ? Sans information ☐ Non ☐ Oui ☐ N° N° N° N° N° N°

En cas d'administration de : médicament dérivé du sang ▶ indiquer sous N°

Nom du prescripteur

Numéro de lot du produit

Service hospitalier dans lequel le produit a été administré

Pharmacie qui a délivré le produit

En cas d'administration de : produits sanguins labiles ▶ préciser leur Dénomination, auteur(s) et/ou Numéro de lot

Effet

Département de survenue

Date de survenue

Durée de l'effet

Nature et description de l'effet : utiliser la cadre AU VERSO

Gravité

☐ Hospitalisation ou prolongation d'hospitalisation
☐ Incapacité ou invalidité permanente
☐ Mise en jeu du pronostic vital
☐ Décès

Evolution

☐ Guérison sans séquelle
☐ Décès dû à l'effet
☐ Décès sans rapport avec l'effet
☐ Sujet non encore rétabli
☐ Guérison avec séquelles
☐ Décès auquel l'effet a pu contribuer
☐ Inconnue

フランス　　副作用報告用紙（裏）

Description de l'effet indésirable :

Les obligations de signalement.

Article R.5144-10
du Code de la Santé publique :

Tout médecin, chirurgien-dentiste ou sage-femme ayant constaté un effet indésirable grave ou inattendu susceptible d'être dû à un médicament ou produit mentionné à l'article R.5144-1, qu'il l'ait ou non prescrit, doit en faire la déclaration immédiate au centre régional de pharmacovigilance.

De même, tout pharmacien ayant eu connaissance d'un effet indésirable grave ou inattendu susceptible d'être dû à un médicament ou produit mentionné à l'article R.5144-1 qu'il a délivré doit également le déclarer aussitôt au centre régional de pharmacovigilance.

Tout membre d'une profession de santé ayant fait la même constatation peut également en informer le centre régional de pharmacovigilance.

Les médicaments dérivés du sang.

Article R.5144-35
du Code de la Santé publique :

Tous les professionnels de santé ayant constaté un effet indésirable susceptible d'être dû à un médicament dérivé du sang doivent en faire la déclaration immédiate dans les conditions prévues à l'article R.5144-10 :

-au centre régional de pharmacovigilance lorsque le médicament a été dispensé dans un établissement de santé au sein duquel est implanté un centre régional de pharmacovigilance ;

-au correspondant local du centre régional de pharmacovigilance lorsque le médicament a été dispensé dans un autre établissement de santé ;

-au centre régional de pharmacovigilance dans les autres cas.

Le rôle des professionnels de santé en matière de pharmacovigilance

1.Notifier au centre de pharmacovigilance du lieu d'exercice du praticien déclarant, le plus rapidement possible :

-toute présomption d'effets indésirables graves ou inattendus, en rapport avec l'utilisation d'un ou plusieurs médicaments,

-toute observation d'effet indésirable lié à un mésusage,

-tout autre effet qu'il juge pertinent de déclarer.

2.Répondre aux demandes du destinataire de la notification en confirmant et complétant celle-ci par écrit, notamment si elle a été transmise oralement ou par téléphone, afin de documenter l'observation initiale.

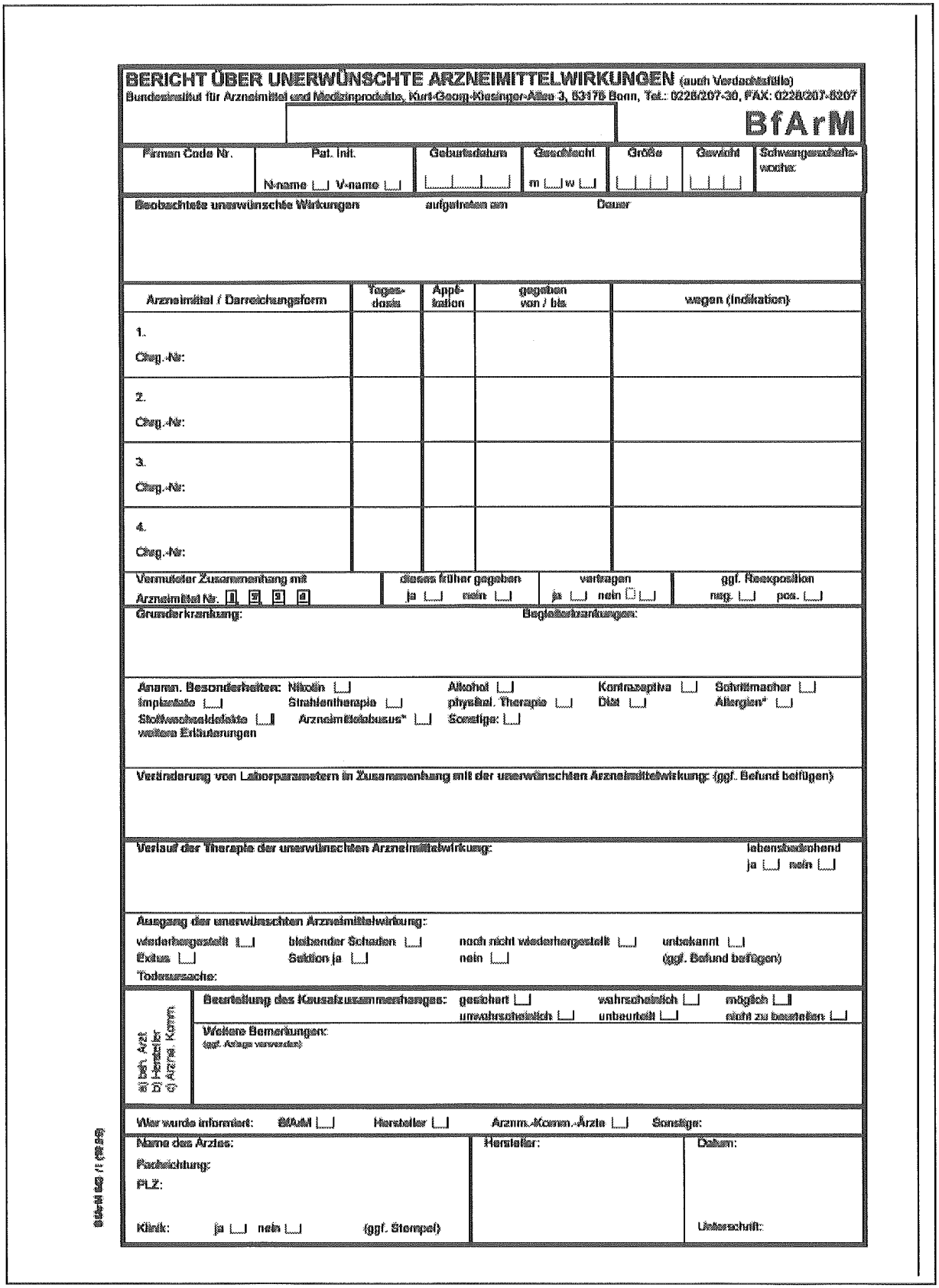
3.Informer les patients en application de la loi du 6 janvier 1978 des déclarations les concernant adressées au centre de pharmacovigilance et à l'Agence du Médicament, et des modalités d'exercice de leur droit d'accès.

4.Conserver les documents concernant l'effet indésirable présumé afin de permettre, en cas de nécessité, de compléter les informations précédemment transmises.

5.Coopérer avec les structures de pharmacovigilance, notamment dans le cadre d'enquêtes particulières.

6.Se tenir informé et tenir compte dans sa pratique professionnelle des données de tolérance des médicaments qu'il prescrit, dispense ou administre.

ドイツ　副作用報告用紙（表）



BERICHT ÜBER UNERWÜNSCHTE ARZNEIMITTELWIRKUNGEN (auch Verdachtsfälle)
Bundesinstitut für Arzneimittel und Medizinprodukte, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Tel.: 0228/207-30, FAX: 0228/207-5207

BfArM

Firmen Code Nr.	Pat. Init. N-name ☐ V-name ☐	Geburtsdatum ☐☐.☐☐.☐☐☐☐	Geschlecht m ☐ w ☐	Größe ☐☐☐	Gewicht ☐☐☐	Schwangerschafts-woche:

Beobachtete unerwünschte Wirkungen | aufgetreten am | Dauer

Arzneimittel / Darreichungsform	Tages-dosis	Appli-kation	gegeben von / bis	wegen (Indikation)
1. Chg.-Nr:				
2. Chg.-Nr:				
3. Chg.-Nr:				
4. Chg.-Nr:				

Vermuteter Zusammenhang mit Arzneimittel Nr. 1 2 3 4 | dieses früher gegeben ja ☐ nein ☐ | vertragen ja ☐ nein ☐ | ggf. Reexposition neg. ☐ pos. ☐

Grunderkrankung: | Begleiterkrankungen:

Anamn. Besonderheiten: Nikotin ☐ Alkohol ☐ Kontrazeptiva ☐ Schrittmacher ☐
Implantate ☐ Strahlentherapie ☐ physikal. Therapie ☐ Diät ☐ Allergien* ☐
Stoffwechselerkrankungen ☐ Arzneimittelabusus* ☐ Sonstige: ☐
weitere Erläuterungen

Veränderung von Laborparametern in Zusammenhang mit der unerwünschten Arzneimittelwirkung: (ggf. Befund beifügen)

Verlauf der Therapie der unerwünschten Arzneimittelwirkung: | lebensbedrohend ja ☐ nein ☐

Ausgang der unerwünschten Arzneimittelwirkung:
wiederhergestellt ☐ | bleibender Schaden ☐ | noch nicht wiederhergestellt ☐ | unbekannt ☐
Exitus ☐ | Sektion ja ☐ | nein ☐ | (ggf. Befund beifügen)
Todesursache:

Beurteilung des Kausalzusammenhanges: gesichert ☐ wahrscheinlich ☐ möglich ☐ unwahrscheinlich ☐ unbeurteilt ☐ nicht zu beurteilen ☐

Weitere Bemerkungen:
(ggf. Anlage verwenden)

a) bes. Arzt b) Hersteller c) Anzmw. Komm.

Wer wurde informiert: BfArM ☐ Hersteller ☐ Anzmw.-Komm.-Ärzte ☐ Sonstige:

Name des Arztes: Fachrichtung: PLZ: Klinik: ja ☐ nein ☐ (ggf. Stempel)	Hersteller:	Datum: Unterschrift:

Stand 11 Seite 1/2

ドイツ　副作用報告用紙（裏）

Bundesinstitut für Arzneimittel
und Medizinprodukte
Kurt Georg-Kiesinger-Allee 3
53175 Bonn
FAX: 0228/207-5207

Hinweise zum Ausfüllen des Berichtbogens
über unerwünschte Arzneimittelwirkungen
nach § 62 des Arzneimittelgesetzes

Das Bundesinstitut für Arzneimittel und Medizinprodukte bittet Sie, Meldungen über unerwünschte Arzneimittelwirkungen auf dem vorliegenden Berichtsbogen BfArM 643 zu erstatten, damit eine rasche Auswertung und EDV-mäßige Bearbeitung gewährleistet ist.

Je vollständiger der Berichtsbogen ausgefüllt wird, um so sicherer wird die Auswertung und Abschätzung eines Arzneimittelrisikos sein können. Unvollständige Daten sollten jedoch kein Hinderungsgrund für eine Meldung sein. Um auch bisher unbekannte Arzneimittelrisiken erfassen zu können, ist es notwendig, auch in Verdachtsfällen und beim Auftreten unerwünschter Wirkungen, die bisher nicht mit den verabreichten Arzneimitteln in Verbindung gebracht wurden, einen Berichtsbogen auszufüllen.

Dem Berichtsbogen können alle Ihnen zu dieser unerwünschten Arzneimittelwirkung, insbesondere über die Symptomatik und den Verlauf zur Verfügung stehende Unterlagen (z.B. Untersuchungsbefunde, Labordaten, Sektionsprotokolle) in Kopie beigelegt werden.

Füllen Sie die Angaben zur Person des Patienten bitte so vollständig wie möglich aus, da hierdurch doppelt gemeldete unerwünschte Wirkungen erkannt werden können. Geben Sie die Initialen des Patienten bitte in der Reihenfolge Name - Vorname an.

Die Daten zu den verabreichten Arzneimitteln sollten so genau wie möglich, d.h. unter Berücksichtigung der vollständigen Bezeichnung (z.B. retard, forte), der Darreichungsform, der Stärke, der Dosierung und der Art der Anwendung (z.B. p.o., i.v., i.m.) angegeben werden. Das Arzneimittel, das vermutlich die unerwünschte Wirkung ausgelöst hat, sollte entsprechend gekennzeichnet werden.
Alle auf dem Berichtsbogen angegebenen patienten- und arztbezogenen Daten werden den Bestimmungen des Bundesdatenschutzgesetzes entsprechend vertraulich behandelt.
Weitere Vordrucke des Berichtsbogens sind beim Bundesinstitut für Arzneimittel und Medizinprodukte, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn erhältlich.

BfArM 643 / 6 (05.99)

イギリス　　副作用報告用紙

In Confidence

COMMITTEE ON SAFETY OF MEDICINES

MCA
MEDICINES CONTROL AGENCY

SUSPECTED ADVERSE DRUG REACTIONS

If you are suspicious that an adverse reaction may be related to a drug or combination of drugs please complete this Yellow Card. For reporting advice please see over. Do not be put off reporting because some details are not known.

PATIENT DETAILS Patient Initials: ..... Sex: M / F Weight if known (kg): .....
Age (at time of reaction): ..... Identification number (Your Practice / Hospital Ref.)*: .....

SUSPECTED DRUG(S)
Give brand name of drug and batch number if known | Route | Dosage | Date started | Date stopped | Prescribed for

.....

.....

SUSPECTED REACTION(S)
Please describe the reaction(s) and any treatment given:

Outcome
Recovered ☐
Recovering ☐
Continuing ☐
Other ☐

Date reaction(s) started: ..... Date reaction(s) stopped: .....
Do you consider the reaction to be serious? Yes / No
If yes, please indicate why the reaction is considered to be serious (please tick all that apply):
Patient died due to reaction ☐ Involved or prolonged inpatient hospitalisation ☐
Life threatening ☐ Involved persistent or significant disability or incapacity ☐
Congenital abnormality ☐ Medically significant; please give details: .....

OTHER DRUGS (including self-medication & herbal remedies)
Did the patient take any other drugs in the last 3 months prior to the reaction? Yes / No
If yes, please give the following information if known:
Drug (Brand, if known) | Route | Dosage | Date started | Date stopped | Prescribed for

.....

.....

.....

.....

.....

Additional relevant information e.g. medical history, test results, known allergies, rechallenge (if performed), suspected drug interactions. For congenital abnormalities please state all other drugs taken during pregnancy and the last menstrual period.

REPORTER DETAILS
Name and Professional Address: .....
.....
.....
Post code: ..... Tel No: .....
Speciality: .....
Signature: ..... Date: .....

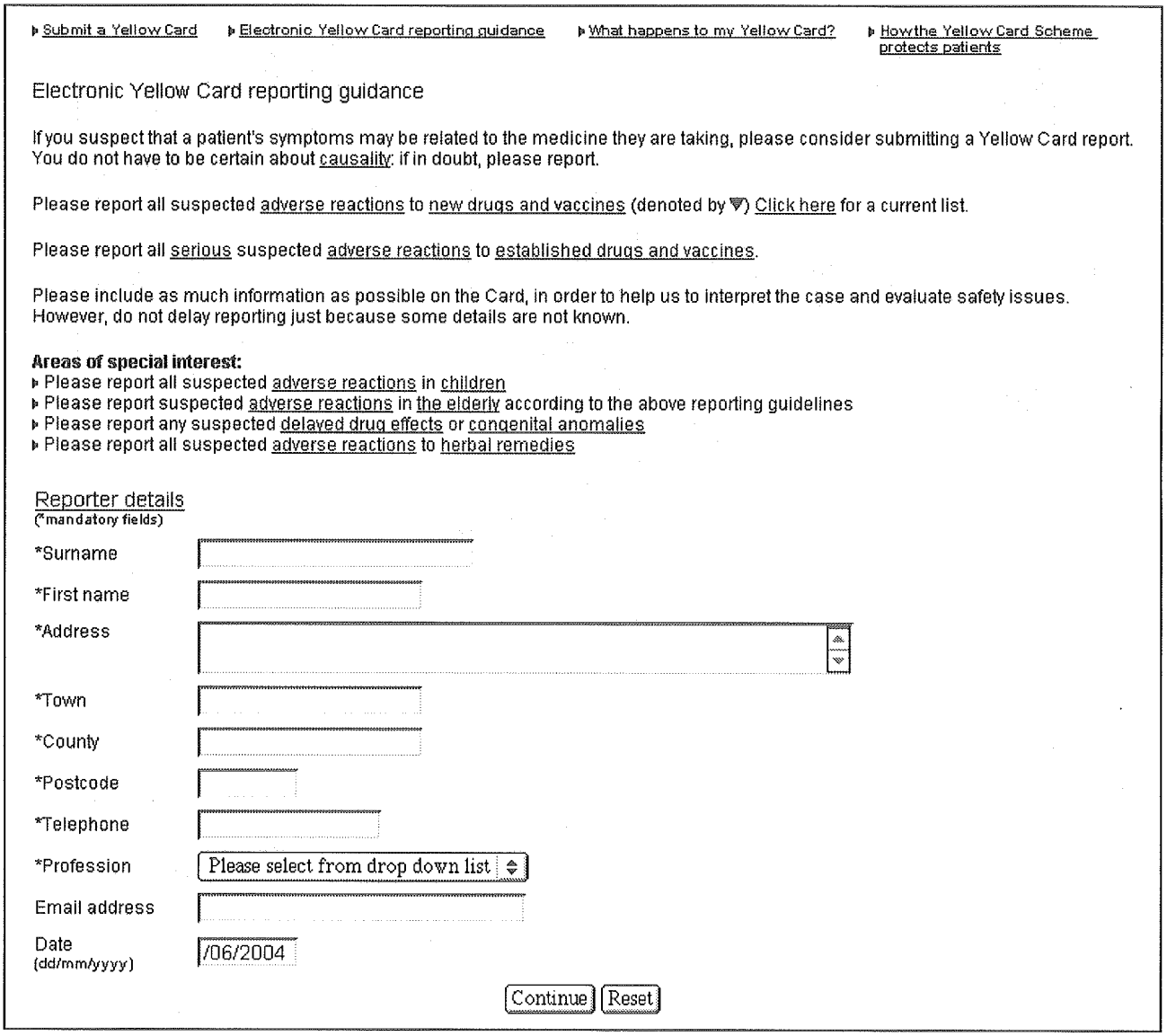
CLINICIAN (if not the reporter)
Name and Professional Address: .....
.....
..... Post code: .....
Tel No: ..... Speciality: .....

If you would like information about other adverse reactions associated with the suspected drug, please tick this box ☐

* This is to enable you to identify the patient in any future correspondence concerning this report

Please attach additional pages if necessary

イギリス　電子的副作用報告



▸ Submit a Yellow Card　▸ Electronic Yellow Card reporting guidance　▸ What happens to my Yellow Card?　▸ Howthe Yellow Card Scheme protects patients

Electronic Yellow Card reporting guidance

If you suspect that a patient's symptoms may be related to the medicine they are taking, please consider submitting a Yellow Card report. You do not have to be certain about causality: if in doubt, please report.

Please report all suspected adverse reactions to new drugs and vaccines (denoted by ▼) Click here for a current list.

Please report all serious suspected adverse reactions to established drugs and vaccines.

Please include as much information as possible on the Card, in order to help us to interpret the case and evaluate safety issues. However, do not delay reporting just because some details are not known.

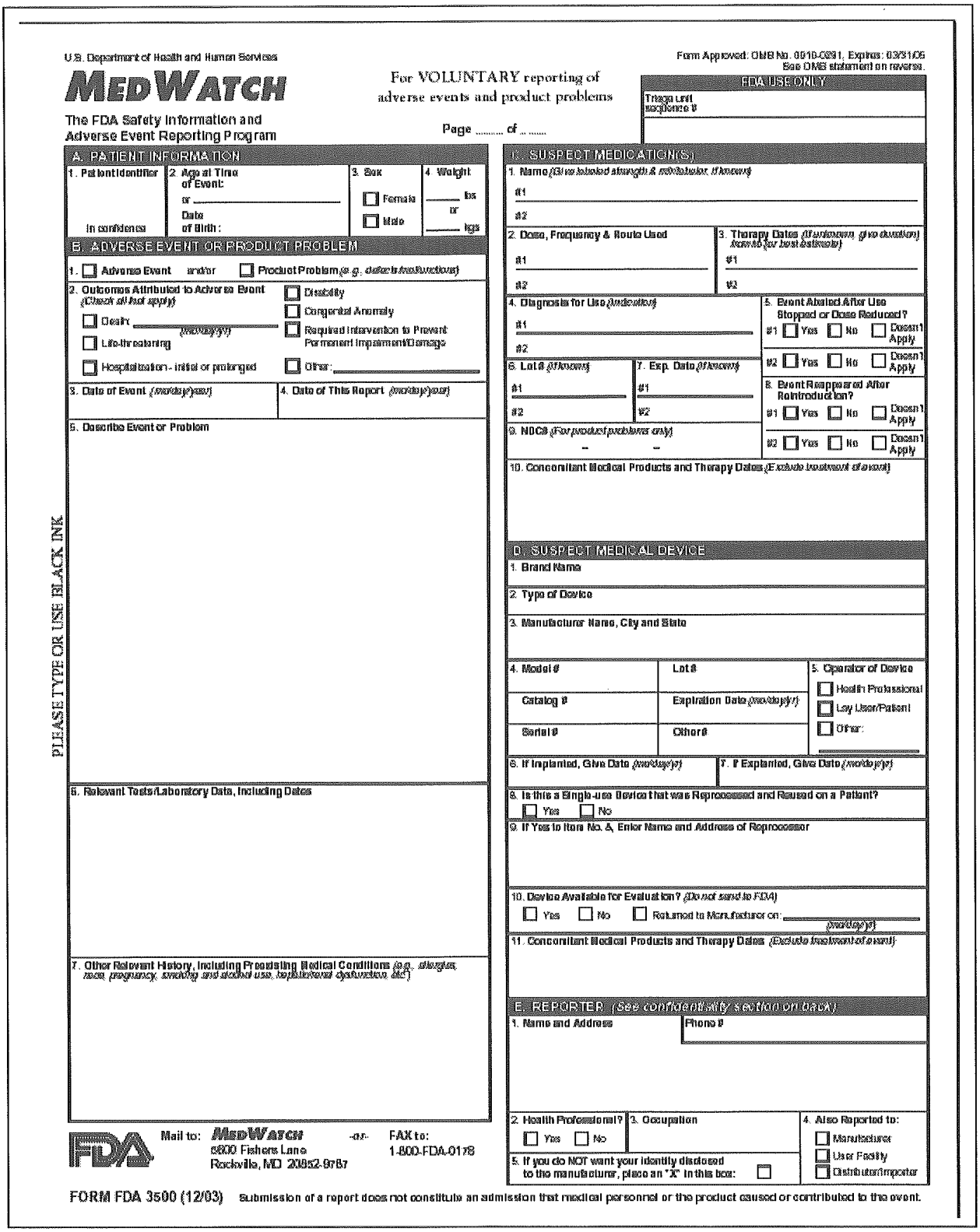
Areas of special interest:
- Please report all suspected adverse reactions in children
- Please report suspected adverse reactions in the elderly according to the above reporting guidelines
- Please report any suspected delayed drug effects or congenital anomalies
- Please report all suspected adverse reactions to herbal remedies

Reporter details
(*mandatory fields)

*Surname
*First name
*Address
*Town
*County
*Postcode
*Telephone
*Profession　Please select from drop down list
Email address
Date (dd/mm/yyyy)　/06/2004

Continue　Reset

アメリカ　副作用報告用紙“FORM FDA 3500”（自発報告用・表）



U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Page ..... of .....

Form Approved: OMB No. 0910-0291, Expires: 03/31/06
See OMB statement on reverse.

FDA USE ONLY
Triage unit
acceptance #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier — In confidence
2. Age at Time of Event: ____ or Date of Birth: ____
3. Sex: ☐ Female ☐ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem (e.g., defect/malfunction)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   ☐ Death ____ (mm/dd/yy)
   ☐ Life-threatening
   ☐ Hospitalization - initial or prolonged
   ☐ Disability
   ☐ Congenital Anomaly
   ☐ Required Intervention to Prevent Permanent Impairment/Damage
   ☐ Other: ____
3. Date of Event (mm/dd/yy)
4. Date of This Report (mm/dd/yy)
5. Describe Event or Problem
6. Relevant Tests/Laboratory Data, Including Dates
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney dysfunction, etc.)

C. SUSPECT MEDICATION(S)

1. Name (Give labeled strength & manufacturer if known)
   #1
   #2
2. Dose, Frequency & Route Used
   #1
   #2
3. Therapy Dates (if unknown, give duration)
   #1
   #2
4. Diagnosis for Use (Indication)
   #1
   #2
5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply
6. Lot # (if known)
   #1
   #2
7. Exp. Date (if known)
   #1
   #2
8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply
9. NDC# (For product problem only)
   – –
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Type of Device
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yy) / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other: ____
6. If Implanted, Give Date (mm/dd/yy)
7. If Explanted, Give Date (mm/dd/yy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. REPORTER (See confidentiality section on back)

1. Name and Address
   Phone #
2. Health Professional? ☐ Yes ☐ No
3. Occupation
4. Also Reported to: ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 -or- FAX to: 1-800-FDA-0178

FORM FDA 3500 (12/03) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

アメリカ　副作用報告用紙“FORM FDA 3500”（自発報告用・裏）

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- Medications *(drugs or biologics)*
- Medical devices *(including in-vitro diagnostics)*
- Special nutritional products *(dietary supplements, medical foods, infant formulas)*
- Cosmetics
- Medication errors

Report product problems - quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures

Report **SERIOUS** adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening *(real risk of dying)*
- Hospitalization *(initial or prolonged)*
- Disability *(significant, persistent or permanent)*
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Just fill in the sections that apply to your report
- Use section C for all products except medical devices
- Attach additional blank pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer *(or both)*

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Important numbers:

- 1-800-FDA-0178 -- To FAX report
- 1-800-FDA-1088 -- To report by phone or for more information
- 1-800-822-7967 -- For a VAERS form for vaccines

To Report via the Internet:

http://www.fda.gov/medwatch/report.htm

The public reporting burden for this collection of information has been estimated to average 30 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 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
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."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FORM FDA 3500 (12/03) (Back)　Please Use Address Provided Below -- Fold in Thirds, Tape and Mail

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL　PERMIT NO. 946　ROCKVILLE MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

アメリカ　副作用報告用紙“FORM FDA 3500A”（義務報告用・表）

Form Approved: OMB No. 0910-0291, Expires: 03/31/06
See OMB statement on reverse.

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

Page ____ of ____

Mfr Report #

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier — In confidence
2. Age at Time of Event: ____ or Date of Birth: ____
3. Sex: ☐ Female ☐ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem (e.g., defect/malfunction)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - ☐ Death ____ (mm/dd/yy)
   - ☐ Life-threatening
   - ☐ Hospitalization - Initial or prolonged
   - ☐ Disability
   - ☐ Congenital Anomaly
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage
   - ☐ Other: ____
3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)
5. Describe Event or Problem
6. Relevant Tests/Laboratory Data, Including Dates
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney dysfunction, etc.)

C. SUSPECT MEDICATION(S)

1. Name (Give strength & manufacturer, if known)
   #1
   #2
2. Dose, Frequency & Route Used
   #1
   #2
3. Therapy Dates (If unknown, give duration) (mm/dd/yy)
   #1
   #2
4. Diagnosis for Use (Indication)
   #1
   #2
5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply
6. Lot # (If known)
   #1
   #2
7. Exp. Date (If known)
   #1
   #2
8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply
9. NDC# (For product problems only)
   - -
   - -
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Type of Device
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yy) / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other ____
6. If Implanted, Give Date (mm/dd/yy)
7. If Explanted, Give Date (mm/dd/yy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

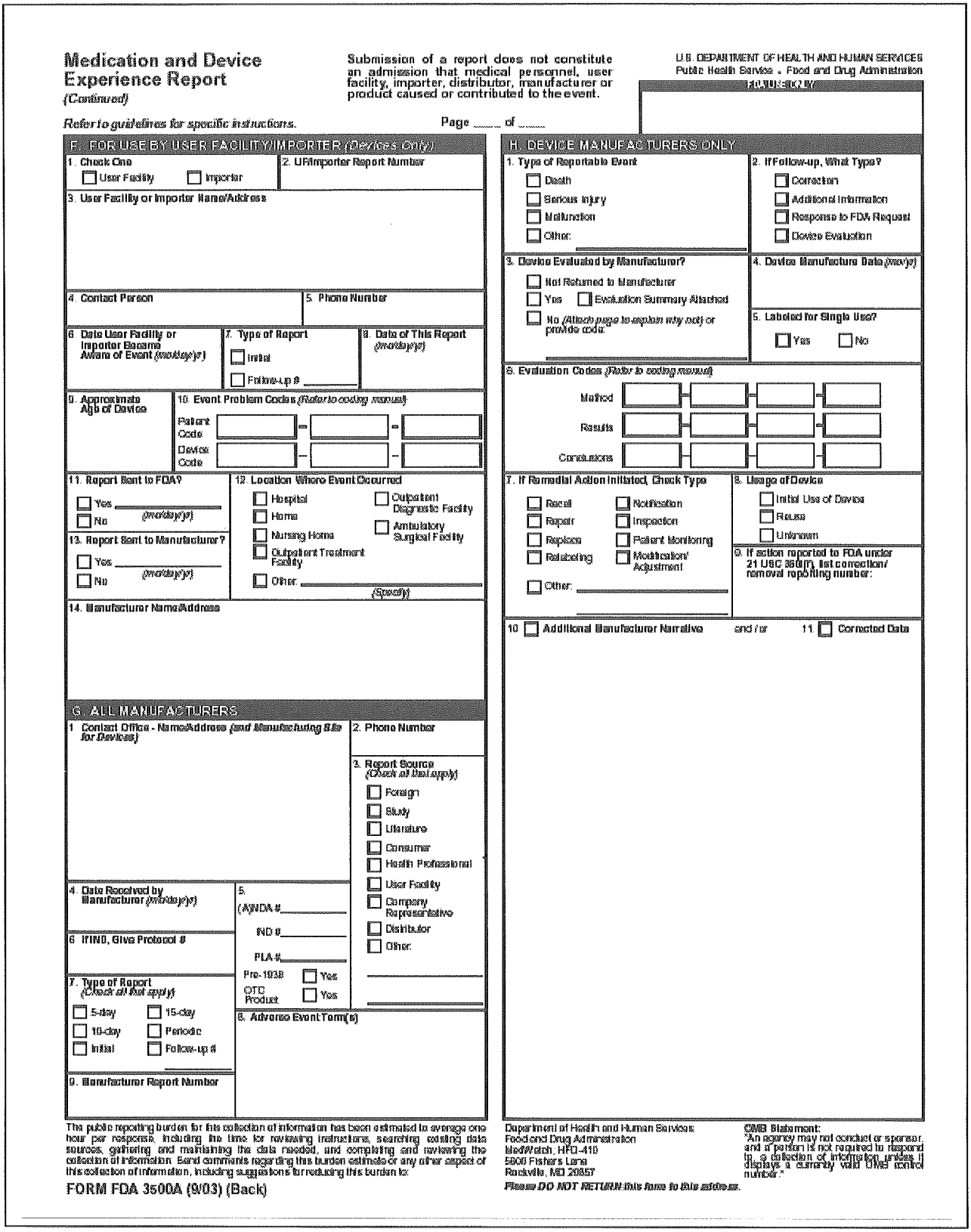
1. Name and Address
   Phone #
2. Health Professional? ☐ Yes ☐ No
3. Occupation
4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☐ Unk.

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

FORM FDA 3500A (9/03)

アメリカ　副作用報告用紙“FORM FDA 3500A”（義務報告用・裏）



Medication and Device Experience Report
(Continued)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

FOR FDA USE ONLY

Refer to guidelines for specific instructions.

Page ____ of ____

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mo/day/yr)*
7. Type of Report ☐ Initial ☐ Follow-up #
8. Date of This Report *(mo/day/yr)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* Patient Code Device Code
11. Report Sent to FDA? ☐ Yes *(mo/day/yr)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes *(mo/day/yr)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*
2. Phone Number
3. Report Source *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mo/day/yr)*
5. (NDA #____ IND #____ PLA #____ Pre-1938 ☐ Yes OTC Product ☐ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)* ☐ 5-day ☐ 15-day ☐ 10-day ☐ Periodic ☐ Initial ☐ Follow-up #
8. Adverse Event Term(s)
9. Manufacturer Report Number

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not or provide code.)*
4. Device Manufacture Date *(mo/yr)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)* Method Results Conclusions
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/ Adjustment ☐ Other:
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360(j), list correction/ removal reporting number:
10. ☐ Additional Manufacturer Narrative *and /or* 11. ☐ Corrected Data

The public reporting burden for this collection of information has been 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:

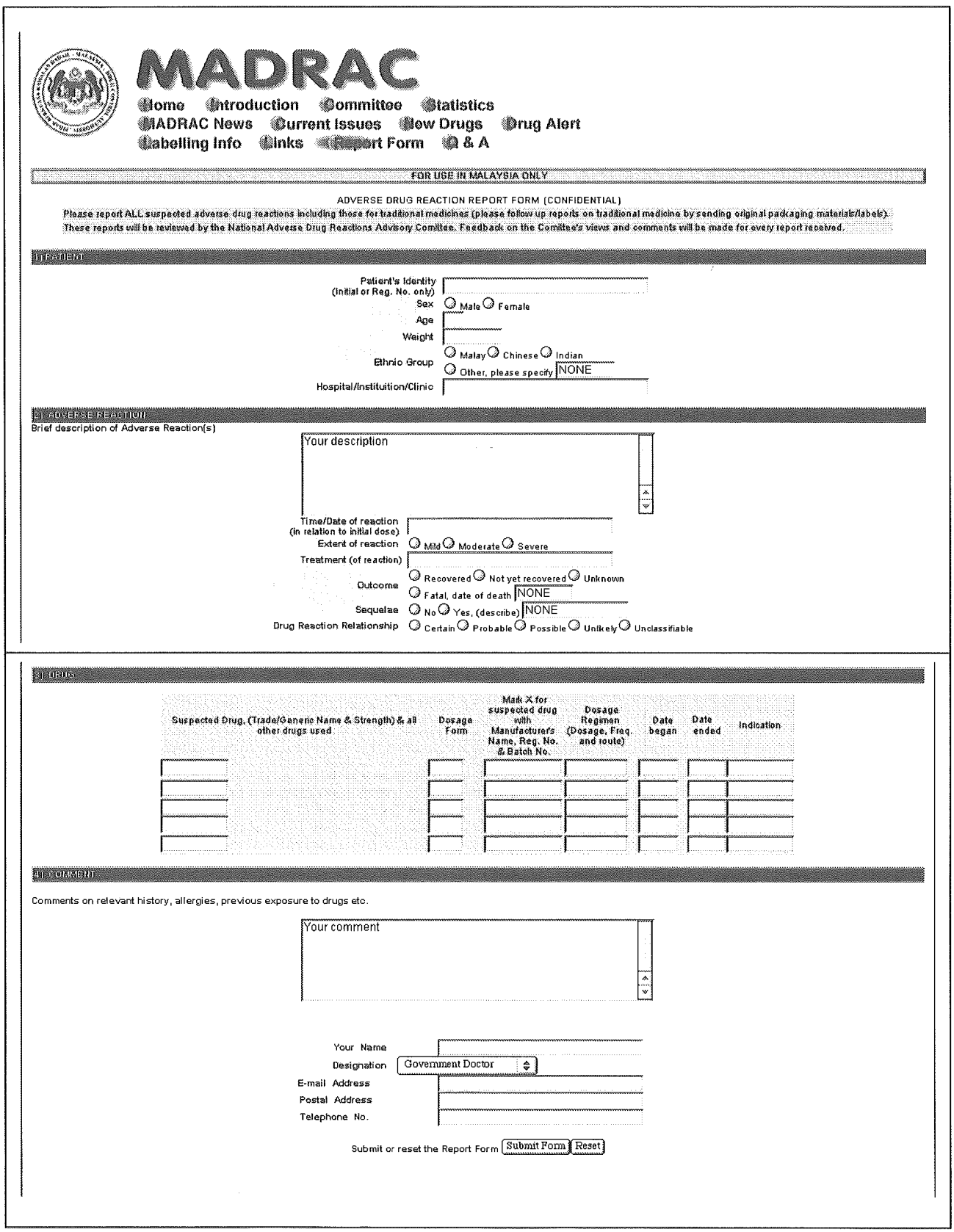
Department of Health and Human Services
Food and Drug Administration
MedWatch, HFD-410
5600 Fishers Lane
Rockville, MD 20857

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."

FORM FDA 3500A (9/03) (Back)

Please DO NOT RETURN this form to this address.

マレーシア　　電子的副作用報告



MADRAC

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MADRAC News Current Issues New Drugs Drug Alert
Labelling Info Links Report Form Q & A

FOR USE IN MALAYSIA ONLY

ADVERSE DRUG REACTION REPORT FORM (CONFIDENTIAL)

Please report ALL suspected adverse drug reactions including those for traditional medicines (please follow up reports on traditional medicine by sending original packaging materials/labels). These reports will be reviewed by the National Adverse Drug Reactions Advisory Comittee. Feedback on the Comittee's views and comments will be made for every report received.

1 | PATIENT

Patient's Identity (Initial or Reg. No. only)
Sex ○ Male ○ Female
Age
Weight
Ethnic Group ○ Malay ○ Chinese ○ Indian ○ Other, please specify NONE
Hospital/Institution/Clinic

2 | ADVERSE REACTION

Brief description of Adverse Reaction(s)

Your description

Time/Date of reaction (in relation to initial dose)
Extent of reaction ○ Mild ○ Moderate ○ Severe
Treatment (of reaction)
Outcome ○ Recovered ○ Not yet recovered ○ Unknown ○ Fatal, date of death NONE
Sequelae ○ No ○ Yes, (describe) NONE
Drug Reaction Relationship ○ Certain ○ Probable ○ Possible ○ Unlikely ○ Unclassifiable

3 | DRUGS

Suspected Drug, (Trade/Generic Name & Strength) & all other drugs used	Dosage Form	Mark X for suspected drug with Manufacturer's Name, Reg. No. & Batch No.	Dosage Regimen (Dosage, Freq. and route)	Date began	Date ended	Indication

4 | COMMENT

Comments on relevant history, allergies, previous exposure to drugs etc.

Your comment

Your Name
Designation Government Doctor
E-mail Address
Postal Address
Telephone No.

Submit or reset the Report Form Submit Form Reset