product or product-use specific, and separate Investigator's Brochures may be used accordingly. However, such documents are expected to cover ADR information that applies to all affected product presentations and uses. When relevant, separate discussions of pertinent product-specific or use-specific safety information will also be included.

It is recommended that any adverse drug reactions that qualify for expedited reporting observed with one product dosage form or use be cross referenced to regulatory records for all other dosage forms and uses for that product. This may result in a certain amount of overreporting or unnecessary reporting in obvious situations (for example, a report of phlebitis on IV injection sent to authorities in a country where only an oral dosage form is studied or marketed). However, underreporting is completely avoided.

3. Poststudy Events

Although such information is not routinely sought or collected by the sponsor, serious adverse *events* that occurred after the patient had completed a clinical study (including any protocol required posttreatment followup) will possibly be reported by an investigator to the sponsor. Such cases should be regarded for expedited reporting purposes as though they were study reports. Therefore, a causality assessment and determination of expectedness are needed for a decision on whether or not expedited reporting is required.

F. Informing Investigators and Ethics Committees/Institutional Review Boards of New Safety Information

International standards regarding such communication are discussed within the ICH GCP Guidelines, including the addendum on "Guideline for the Investigator's Brochure." In general, the sponsor of a study should amend the Investigator's Brochure as needed, and in accord with any local regulatory requirements, so as to keep the description of safety information updated.

Attachment 1

Key Data Elements for Inclusion in Expedited Reports of Serious Adverse Drug Reactions

The following list of items has its foundation in several established precedents, including those of CIOMS-I, the WHO International Drug Monitoring Centre, and various regulatory authority forms and guidelines. Some items may not be relevant depending on the circumstances. The minimum information required for expedited reporting purposes is: an identifiable patient, the name of a suspect medicinal product, an identifiable reporting source, and an event or outcome that can be identified as serious and unexpected and for which, in clinical investigation cases, there is a reasonable suspected causal relationship. Attempts should be made to obtain followup information on as many other listed items pertinent to the case.

1. Patient Details:

• Initials,

• Other relevant identifier (clinical investigation number, for example),

- Gender,
- Age and/or date of birth,
- Weight,
- Height.
- 2. Suspected Medicinal Product(s):
 - · Brand name as reported,
- International Nonproprietary Name (INN).
 - Batch number,
- Indication(s) for which suspect medicinal product was prescribed or tested,
- Dosage form and strength,
- Daily dose and regimen (specify units—
- e.g., mg, mL, mg/kg)
 - Route of administration,
 - Starting date and time of day,

• Stopping date and time, or duration of treatment.

3. Other Treatment(s):

• For concomitant medicinal products (including nonprescription/OTC medicinal products) and nonmedicinal product therapies, provide the same information as for the suspected product.

4. Details Of Suspected Adverse Drug Reaction(s)

• Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious should be given. In addition to a description of the reported signs and symptoms, whenever possible, attempts should be made to establish a specific diagnosis for the reaction.

Start date (and time) of onset of reaction,

• Stop date (and time) or duration of reaction,

• Dechallenge and rechallenge information, • Setting (e.g., hospital, out-patient clinic, home, nursing home),

• Outcome: Information on recovery and any sequelae; what specific tests and/or treatment may have been required and their results; for a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction should be provided. Any autopsy or other post-mortem findings (including a coroner's report) should also be provided when available. Other information: anything relevant to facilitate assessment of the case, such as medical history, including allergy, drug or alcohol abuse; family history; findings from special investigations.

5. Details on Reporter of Event (Suspected ADR):

- Name,
- Address,
- Telephone number,
- Profession (specialty).

6. Administrative and Sponsor/Company Details:

• Source of report: was it spontaneous, from a clinical investigation (provide details),

from the literature (provide copy), other? • Date event report was first received by sponsor/manufacturer,

• Country in which event occurred,

- Type of report filed to authorities: initial
- or followup (first, second, etc.).
 - Name and address of sponsor/

manufacturer/company,

• Name, address, telephone number, and FAX number of contact person in reporting company or institution,

• Identifying regulatory code or number for marketing authorization dossier or clinical investigation process for the suspected product (for example, IND or CTX number, NDA number).

• Sponsor/manufacturer's identification number for the case. (This number should be the same for the initial and followup reports on the same case.)

Dated: February 23, 1995.

William B. Schultz,

Deputy Commissioner for Policy. [FR Doc. 95–4961 Filed 2–28–95; 8:45 am] BILLING CODE 4160–01–F