

TABLE 4.—HIGHLIGHTS OF PROPOSED CHANGES TO FDA'S SAFETY REPORTING REQUIREMENTS—Continued

| 21 CFR Section | Proposed Change (reference in section III of this document) | Is the change based on ICH (ICH guidance)? |
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| Changes only apply to 310.305, 314.80, 314.98, and 600.80. | <ul style="list-style-type: none"> Always expedited reports for certain medically significant SADRs whether unexpected or expected and whether or not the SADR leads to a serious outcome (D.4). Expedited report for medication errors (D.5) 30-day followup report for initial serious and unexpected SADR reports, always expedited reports, and medication error reports that do not contain a full data set (D.6). | No |
| | <i>Other Changes</i> | No |
| | Active query required to acquire certain safety information (A.6, C.5, D.6, D.7). | No |
| | Full data set required for reports of serious SADRs, always expedited reports, and medication error reports (A.5, C.5, D.1, D.4, D.5, E.4). | No |
| | Safety reporting requirements for contractors and shared manufacturers (A.4, D.9). | No |
| | Reporting requirements for spontaneous reports codified (A.7, C.6) | Yes (E2A and E2C) |
| | Supporting documentation required for expedited reports concerning a death or hospitalization (D.7). | No |
| | FDA request for submission of safety reports at times other than prescribed by regulations (C.4). | No |
| | Individual case safety reports required to be coded using MedDRA (F.2). | Yes (M1) |
| | SADR information from class action lawsuits (A.7, E.1.e, E.2.k.v, E.3) | No |
| Changes only to apply to 314.80, 314.98 and 600.80. | Contact person for postmarketing safety reports (E.1.h, E.2.k.xi, E.3, F.4) | No |
| | Use of computer-generated facsimile of FDA Form 3500A or VAERS form permitted without approval by FDA (F.5). | No |
| | Location of safety records (D.10, E.1.g, E.2.k.x, E.3) | No |
| | FDA request for submission of safety related records (D.7, H). | No |
| | <i>New or Revised Safety Reports</i> | No |
| | Semiannual submission of certain spontaneously reported individual case safety reports (E.4, E.5.a). | No |
| | TPSR, PSUR, or IPSR for applications approved prior to January 1, 1998 (E.1, E.2, E.3, E.5.a). | No |
| | PSUR/IPSR for applications approved on or after January 1, 1998 (E.2, E.3, E.5.a). | Yes (E2C) |
| | PSUR/IPSR for pediatric use supplements (E.5.a) | No |
| | <i>Other Changes</i> | Yes (E2C) |
| Change only applies to 314.81 and 601.28 ² . | Periodicity of periodic safety reports (E.5.a, I) | Yes (E2C) |
| | Submission date for periodic safety reports (A.10, E.5.b, I) | Yes (E2C) |
| | CCSI for determination of listed and unlisted SADRs for certain periodic safety reports (A.9, E.2, E.3, E.4). | Yes (E2C) |
| | Information in addition to the minimum data set not required to be acquired for nonserious SADRs, except for nonserious SADRs resulting from a medication error, which require a full data set (A.3, C.5, E.4). | No |
| | Individual case safety reports forwarded to applicant by FDA required to be included in comprehensive safety analysis (C.2). | No |
| | Information on resistance to antimicrobial drug products (E.2.k.vii, E.3) | No |
| | Number of copies of periodic safety reports required to be submitted to FDA (C.3). | No |
| | Requirement to submit safety-related information in postmarketing annual report revoked (J). | No |
| | Investigator safety reporting requirements revised | No |
| | Submission of expedited safety reports required for human bioequivalence and bioavailability studies which are exempt from submission of an IND (K). | No |
| Change only applies to 312.64(b) ³ | | |
| Change only applies to 320.31(d) ⁴ | | |
| Change only applies to 606.170 ⁵ | All serious SARs required to be submitted to FDA for blood and blood products (D.12). | No |

¹ Section 310.305 describes postmarketing safety reporting regulations for prescription drug products marketed for human use without an approved application; § 312.32 describes premarketing safety reporting regulations for investigational drugs and biological products; § 314.80 describes postmarketing safety reporting regulations for human drugs with approved NDAs; § 314.98 describes postmarketing safety reporting regulations for human drugs with approved ANDAs; and § 600.80 describes postmarketing safety reporting regulations for human licensed biological products with approved BLAs.

² Section 314.81 describes postmarketing annual reporting regulations for human marketed drugs with approved NDAs; § 601.28 describes postmarketing annual reporting regulations for pediatric studies of human licensed biological products with approved BLAs.

³ Section 312.64(b) describes requirements for safety reporting to sponsors by investigators.

⁴ Section 320.31 (d) describes bioequivalence and bioavailability requirements for studies which are exempt from submission of an IND.

⁵ Section 606.170 describes safety reporting and recordkeeping requirements for blood and blood products.