

the signature block be for the certifier and contractor as well.

The agency agrees with the need for clarification regarding who must certify and has incorporated language in the final rule to address this suggestion. Under the final rule, the president, chief executive officer, executive officer, U.S.-designated agent of a foreign manufacturer or other official most directly responsible for the firm's operations shall certify reports submitted under section 519 of the act.

58. Two comments requested that decentralized certification be allowed for multisite firms. Another comment suggested that centralized reports be used in this situation.

Manufacturers have the option of certifying centrally or on a decentralized basis. Firms deciding to certify centrally must identify the sites covered by the certificate by name and registration number or FDA-assigned identification number.

#### *H. Additional Requirements (§ 803.15)*

59. A few comments asserted that these provisions are vague and inappropriate in the absence of a device failure complaint.

The agency disagrees. This provision refers to submission of additional information after an adverse event report has been filed. Accordingly, FDA would not be requesting information in the absence of a device failure or complaint.

60. A few comments objected to the idea of giving FDA unlimited access to data. One comment wanted to restrict FDA's right to copy data and another wanted an appeal process.

FDA does not agree with comments proposing to restrict or limit the agency's access to additional information about adverse events. Under section 704(e) of the act, every person who is required to maintain records under section 519 of the act and every person who is in charge or custody of such records must permit FDA at all reasonable times to have access to and to copy and verify such records. Failure to provide such information may be a violation of section 301 of the act and may subject a person to civil or criminal penalties. Section 704(e) of the act does not limit in any way the types of device records maintained under section 519 of the act that FDA may inspect.

FDA does not agree that the agency should be required to provide an appeal process with respect to requests for additional information. As described above, FDA has statutory authority to require additional information concerning adverse events. Moreover,

such information needs to be provided as quickly as possible to enable FDA to take appropriate action.

61. Several comments suggested the regulation be modified to remove the requirement that each reportable event be investigated because in some instances an investigation is unnecessary.

The agency disagrees. All reportable events must be investigated by the manufacturer. The scope of an investigation may vary according to the circumstances; however, an investigation must be able to adequately assess the cause of the event. Sections 820.162 and 820.198 of FDA's CGMP regulations require manufacturers to review, evaluate and investigate any complaint involving the failure of a device to meet its performance specifications or involving injury, death, or any hazard to safety. FDA considers any event that must be reported under this part to be a death, injury, or hazard to safety.

#### *I. Exemptions, Variances, and Alternative Reporting Requirements (§ 803.19)*

62. One comment asked that alternative reporting requirements under the current MDR system be incorporated into this regulation. One comment stated that the criteria for alternative reporting should be clarified.

FDA has incorporated the alternative reporting options from the MDR regulation issued in 1984 and expanded the options available in this regulation. Under the final regulation, FDA may grant a written exemption, variance, or alternative to some or all of the requirements when it determines compliance with all MDR requirements is not necessary to protect the public health. Examples of situations include: (1) Devices for which FDA is already aware of a type of malfunction and appropriate action has been taken to protect the public health, such as a recall, removal, or other correction; (2) adverse events that are known and well documented, are occurring at a normal rate, and do not justify the initiation of remedial action; and (3) device events occurring on an infrequent basis or where a longer period for investigation or followup is appropriate and necessary.

In these cases, FDA may impose conditions on its approval of an exemption, variance, or alternative reporting mechanism, including the requirement to report on a less frequent basis than otherwise required or to provide summary data rather than individual reports. The final regulation, upon its effective date, will supersede

all previously granted exemptions and variances from the 1984 reporting requirements. The agency intends to review all current exemptions and variances and notify relevant parties about the status of their exemptions and variances and the additional steps that may be necessary to conform to the new requirements effected by this regulation.

63. A few comments stated the criteria for exemption are unclear, especially with respect to investigational device exemptions, and thus create a loophole.

The criteria for exemptions (§ 803.19) are based upon interpretations of the act as to the types of entities Congress intended should be subject to reporting. FDA believes these exemptions are reasonably clear. The exemptions specifically granted under this final regulation are the same as those in the MDR regulation issued in 1984. Devices subject to investigational device exemptions are subject to reporting under the regulations governing that process (parts 812 and 813). The exception to this are devices with investigational device exemptions that are approved for export. These devices are considered to be in commercial distribution and, therefore, subject to MDR.

#### *J. Where To Submit a Report (§ 803.12)*

64. There were only two comments on this section. One suggested that "MDR" be added to the mailing address. The other recommended the use of electronic reporting.

The agency agrees with these comments. "MDR" has been added to the mailing address. In addition, the agency, with prior approval, will accept required reports submitted electronically or on reporting media such as magnetic disc or tape in accordance with § 803.14(a). The agency is in the process of developing standards, guidelines, or procedures for the format to be used with electronic reports. Once available, any electronic reporting system meeting such criteria will be deemed to have prior FDA approval.

#### *K. Written MDR Procedures (§ 803.17)*

65. A few comments requested additional guidance on written MDR procedures.

FDA agrees and has developed guidance concerning MDR procedures. Requests for this guidance should be directed to:

Division of Small Manufacturers Assistance (HFZ-220), Office of Health and Industry Programs, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850.