(1) A copy of the information you provided,

(2) The date the information was received by you,

(3) The date the information was provided to the other constituent part applicant(s), and

(4) The name and address of the other constituent part applicant(s) to whom you provided the information.

§ 4.104 How and where must you submit postmarketing safety reports for your combination product or constituent part?

(a) If you are a constituent part applicant, you must submit postmarketing safety reports in accordance with the regulations identified in § 4.102(b) that are applicable to your product based on its application type.

(b) If you are a combination product applicant, you must submit postmarketing safety reports required under § 4.102 in the manner specified in the regulation applicable to the type of report, with the following exceptions:

(1) You must submit the postmarketing safety reports identified in § 4.102(c)(1)(i) and (ii) in accordance with § 314.80(g) of this chapter if your combination product received marketing authorization under an NDA or ANDA or in accordance with § 600.80(h) of this chapter if your combination product received marketing authorization under a BLA.

(2) You must submit the postmarketing safety reports identified in § 4.102(c)(2)(ii) and (c)(3)(ii) in accordance with § 803.12(a) of this chapter if your combination product received marketing authorization under a device application.

§ 4.105 What are the postmarketing safety reporting recordkeeping requirements for your combination product or constituent part?

(a) If you are a constituent part applicant:

(1) You must maintain records in accordance with the recordkeeping requirements in the applicable regulation(s) described in § 4.102(b).

(2) You must maintain records required under § 4.103(b) for the longest time period required for records under the postmarketing safety reporting regulations applicable to your product under § 4.102(b).

(b) If you are a combination product applicant, you must maintain records in accordance with the longest time period required for records under the regulations applicable to your product under § 4.102.

PART 5—ORGANIZATION

Subparts A–L [Reserved]

Subpart M—Organization

Sec.

AUTHORITY: 5 U.S.C. 552; 21 U.S.C. 301–397.

SOURCE: 77 FR 15962, Mar. 19, 2012, unless otherwise noted.

Subparts A–L [Reserved]

Subpart M—Organization

§ 5.1100 Headquarters.

Office of the Commissioner.[1]
Office of the Chief Counsel.
Office of the Executive Secretariat.
  Freedom of Information Staff.
  Dockets Management Staff.
Office of the Chief Scientist.[1]
Office of Counter-Terrorism and Emerging Threats.
Office of Scientific Integrity.
Office of Regulatory Science and Innovation.
  Division of Science Innovation and Critical Path.
  Division of Scientific Computing and Medical Information.
Office of Scientific Professional Development.
Office of Health Informatics.
Office of Women's Health.
Office of External Affairs.
  Office of Media Affairs.
  Office of Communications.
  Office of Health and Constituent Affairs.
Office of Minority Health.
National Center for Toxicological Research.[2]
  Office of the Center Director.
  Office of Management.
  Office of Research.
  Division of Biochemical Toxicology.
  Division of Genetic and Molecular Toxicology.

[1] Mailing address: 10903 New Hampshire Ave., Silver Spring, MD 20993.

[2] Mailing address: Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079.