The 1995 proposed rule provided a 90-day comment period (extended to 144 days in the Federal Register of October 16, 1995, 60 FR 53560). As discussed previously, the revised burden hour estimates in the final rule are based partially on comments received.

The information collection provisions in the proposed rule were approved under OMB no. 0910–0312. Because of changes made since the proposed rule, FDA has submitted the information collection provisions of the final rule to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule.

XVII. Congressional Review

This final rule has been determined to be a major rule for purposes of 5 U.S.C. 801 *et seq.*, Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121). FDA is submitting the information and reports as required by that statute.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 804

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 897

Advertising, Cigarettes, Labeling, Sale and distribution, Smokeless tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801, 803, 804, 807, and 820 are amended and a new part 897 is added as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. Section 801.126 is added to subpart D to read as follows:

§ 801.126 Exemptions for cigarettes and smokeless tobacco.

Cigarettes and smokeless tobacco as defined in part 897 of this chapter are exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act.

PART 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

4. Section 803.19 is amended by adding new paragraphs (f) and (g) to read as follows:

§ 803.19 Exemptions, variances, and alternative reporting requirements.

* * * * *

(f) Manufacturers as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process.

(g) User facilities are exempt from submitting medical device reports concerning cigarettes and smokeless tobacco under this part.

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

5. The authority citation for 21 CFR part 804 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

6. Section 804.25 is amended by adding a new paragraph (c) to read as follows:

§ 804.25 Reports by distributors.

* * * * *

(c) Distributors as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for adverse events related to contamination.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

7. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

8. Section 807.65 is amended by adding a new paragraph (j) to read as follows:

§ 807.65 Exemptions for device establishments.

* * * * *

(j) Distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

PART 820—GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES: GENERAL

9. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: Secs. 501, 502, 515, 518, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360e, 360h, 360i, 360j, 371, 374).

10. Section 820.1 is amended by adding and reserving new paragraph (e) and adding new paragraph (f) to read as follows:

§ 820.1 Scope.

* * * * *

(e) [Reserved]

(f) This part does not apply to distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

11. New part 897 is added to read as follows:

PART 897—CIGARETTES AND SMOKELESS TOBACCO

Subpart A—General Provisions

Sec.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age