

## XII. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday. FDA has verified the Web site addresses in this document, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. U.S. Census Bureau, 2000 County Business Patterns, available at <http://www.census.gov/epcd/cbp/view/cbpview.html>.
2. U.S. Census Bureau, 1999 Nonemployer Statistics, available at <http://www.census.gov/epcd/nonemployer/index.html>.
3. U.S. Food and Drug Administration, Field Accomplishments and Compliance Tracking System (FACTS), Fiscal year 2002.
4. U.S. Food and Drug Administration, Operational and Administrative System for Import Support (OASIS), Fiscal year 2002.
5. Impact Marketing Consultants, The Rauch Packaging Guide to the U.S. Packaging Industry, the fourth edition, 2002.
6. U.S. Department of Agriculture, National Agriculture Statistics Service, 1997 Census of Agriculture-U.S. Data, available at <http://www.nass.usda.gov/census/>.
7. Brown, Bradley, Memorandum to the file, November 22, 2002.
8. U.S. Small Business Administration, Office of Advocacy, Small Business by the Numbers, May, 2002, available at <http://www.sba.gov/advo/stats/sbfaq.html>.
9. U.S. Department of Labor, Bureau of Labor Statistics, National Compensation Survey: Occupation Wages in the United States, 2000, summary 01-04, available at <http://www.bls.gov/ncs/ocs/sp/ncbl0354.pdf>.
10. U.S. Office of Personnel Management, Salary table 2002-DCB, available at <http://www.opm.gov/oca/02tables/02DCB.pdf>, accessed on 9/24/2002.
11. NUA, How Many Online? available at [http://www.nua.com/surveys/how\\_many\\_online/index.html](http://www.nua.com/surveys/how_many_online/index.html), accessed on 9/4/2002.
12. Williams, V., U.S. Small Business Administration, Office of Advocacy, E-commerce, Small Businesses Venture Online, July, 1999, available at [http://www.sba.gov/advo/stats/e\\_comm.pdf](http://www.sba.gov/advo/stats/e_comm.pdf), accessed on 9/31/2002.
13. Dun and Bradstreet, D&B, 21st Annual Small Business Survey Summary Report, available at <http://sbs.dnb.com/?referrer=sbsnavcenter>, accessed on 9/31/2002.
14. The English Speaking Union, Frequently Asked Questions, available at <http://www.esu.org/faqs.html>, accessed 9/4/2002.
15. U.S. Census Bureau, Popclock, available at <http://www.census.gov/main/www/popclock.html>, accessed on 11/22/2002.
16. Estrin, A., Memorandum to the file, 10/04/2002.
17. Jessup, A., Memorandum to the file, 11/21/2002.

18. Pope, Angela, Memorandum to the file, 10/7/2002.

19. Hennessy, T. W., C. W. Hedberg, L. Slutsker, et al., "A National Outbreak of *Salmonella enteritidis* Infections From Ice Cream," *The New England Journal of Medicine*, May 16, 1996, 1281-1286.
20. Cutler, D. and E. Richardson, 1999, "Your Money and Your Life: The Value of Health and What Affects It," Working Paper 6895, National Bureau of Economic Research.
21. Zorn, D. and K. Klontz, 1998, Appendix: The Value of Consumer Loss to Foodborne Reactive Arthritis," 63 FR 24292-24299, 63, May 1, 1998.
22. Scharff, R. and A. Jessup, "Valuing Chronic Disease for Heterogeneous Populations: the Case of Arthritis," 2002, Mimeo.
23. Lee, L. A., S. M. Ostroff, H. B. McGee, et al., "An Outbreak of Shigellosis at an Outdoor Music Festival," *American Journal of Epidemiology*, 133:6:608-615.
24. Trook, T. J., R. V. Tauxe, R. P. Wise, et al., "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars," *The Journal of the American Medical Association*, 278:5:389-397.
25. Kolavic S. A., A. Kimura, S. L. Simons, et al., "An Outbreak of *Shigella dysenteriae* Type 2 Among Laboratory Workers Due to Intentional Food Contamination," *The Journal of the American Medical Association*, 278:5:396-403.
26. Colley D. G., Widespread Foodborne Cyclosporiasis Outbreaks Present Major Challenges (letter), *Emerging Infectious Diseases*, 2:4:354-356.
27. Herwaldt, B. L., M. L. Ackers, and Cyclospora Working Group, "An Outbreak in 1996 of Cyclosporiasis Associated With Imported Raspberries," *New England Journal of Medicine*, May 29, 1997, 1548-1556.

### List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

### PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart H is added to part 1 to read as follows (subparts F and G are reserved):

#### Subparts F-G [Reserved]

#### Subpart H—Registration of Food Facilities

##### General Provisions

Sec.

- 1.225 Who must register under this subpart?

- 1.226 Who is exempt from this subpart?  
1.227 What definitions apply to this subpart?

#### Procedures for Registration of Food Facilities

- 1.230 When must you register?  
1.231 How and where do you register?  
1.232 What information is required in the registration?  
1.233 What optional items are included in the registration form?  
1.234 How and when do you update your registration information?

#### Additional Provisions

- 1.240 What other registration requirements apply?  
1.241 What happens if you fail to register?  
1.242 What does assignment of a registration number mean?  
1.243 Is food registration information available to the public?

#### General Provisions

##### § 1.225 Who must register under this subpart?

(a) You must register under this subpart if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless you qualify for one of the exemptions in § 1.226.

(b) An owner, operator, or agent in charge of a domestic facility must register whether or not the food from the facility enters interstate commerce.

(c) An owner, operator, or agent in charge of a foreign facility must register the facility. A foreign facility may designate its U.S. agent as its agent in charge for purposes of registering the facility.

##### § 1.226 Who is exempt from this subpart?

This subpart does not apply to the following facilities:

(a) Foreign facilities, if food from such facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. This exemption does not apply to a facility if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature;

- (b) Farms;  
(c) Retail facilities;  
(d) Restaurants;

(e) Nonprofit food facilities in which food is prepared for, or served directly to, the consumer;

(f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing