

Good Manufacturing Practices For Dietary Supplements

by Leanne Wylet, B.A.

The Dietary Supplement Health and Education Act (DSHEA) does not adequately protect U.S. consumer access to dietary supplements. Section 202 includes the following: “The secretary of Health and Human Services should support the Office of the United States Trade Representative, . . . in efforts to move toward the acceptance of mutual recognition relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives and the regulation of good manufacturing practices, between the European Union and the United States.”¹ Dietary supplements, although not specifically listed, are not excluded. “The FDA is now citing the DSHEA reference to “good manufacturing practices” as justification for applying Q7A ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, to food supplements.² Another document which threatens our access to therapeutic food supplements is the Mutual Recognition Agreement signed by the US and the EU on May 18, 1998.³

Q7A ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, “prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH),”⁴ refers to pharmaceuticals as “Active Pharmaceutical Ingredients,” (APIs) a term broad enough to include food supplements if allowed by law. A public meeting to discuss the impact of the FDA GMPs on small businesses was held July 12, 1999,² supposedly satisfying the FDA’s responsibility to small businesses.

The Mutual Recognition Agreement Act (MRA), will produce a single set of dietary supplement standards to be adopted by the World Health Organization (WHO). After a three-year transition period, which began December 7, 1998, European Conformity Assessment Bodies (CABs) will be authorized to serve as inspectors for the FDA.

A flood of recent news articles focuses on risks from overdosing of “nutraceuticals,” which by current definition includes safe, therapeutic doses of vitamins and minerals many consumers have taken for years.

- 1 DSHEA, Section 202, See also: Harris, Suzanne, JD; “S/830, The Federal Food, Drug and Cosmetic act: Asking the Right Questions, Finding the Right Answers,” <http://www.iahf.com>
- 2 FDA Weekly, May, 21 1999 cited by Howe, Kenneth *Chronicle* staff writer; “Herb Remedies: Panacea or Problem”, Kenneth Howe, *San Francisco Chronicle*, June 2, 1999.
- 3 Horton, Linda; “US - EU Mutual Recognition Agreement,” <http://www.citizensvoice.org/course/jham01.rm> You may contact, Linda Horton, lhorton@oc.fda.gov Phone: (301) 827-3344 Fax: (301) 443-6906 or John Stigi, JFS@cdhrh.fda.gov Phone: (301) 443-0836, Fax: (301) 443-8818.
- 4 “International Conference on Harmonization: Draft Guidance on Good Manufacturing Practice for Active Pharmaceutical Ingredients; Availability,” [Docket No. 00D-1418] *The Federal Register*, August 1, 2000

(Copies of the draft guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch [HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER),

1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844, FAX 888-CBERFAX. Send two self-addressed labels to assist the office in processing your requests. Interested persons may submit comments to the Dockets Management Branch (HFA-305) online or offline by downloading a comments template.

Both methods are accessible on the FDA web site at <http://www.fda.gov/ohrms/dockets>.

3Howe, Kenneth; "Herb Remedies: Panacea or Problem", Kenneth Howe, Chronicle Staff Writer reports, ". . . Congress passed the 1994- Dietary Supplement Health and Education Act authorizing the FDA to establish GMP's for herbal products."

<http://www.citizensvoice.org/course/jham01.rm> Pharmaceutical, US - EU Mutual Recognition Agreement, Linda Horton, lhourton@oc.fda.gov Phone: (301) 827-3344 Fax: (301) 443-6906 or John Stigi, JFS@cdrh.fda.gov Phone: (301) 443-0836, Fax: (301) 443-8818.

This explains why we continue to see blocked a Codex Oversight Hearing for being out of compliance with US laws.

The Patients' Voice, Leanne Wylet, Spring 2002, The Patients' Voice, www.pfamhealth.net