Reading Materials and Resources

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Dietary Supplement FDA Information Sources

General Information:

- FDA general dietary supplement Web Site
  http://www.cfsan.fda.gov/~dms/supplmnt.html

Adverse Event Reporting:

- Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act
  http://www.cfsan.fda.gov/~dms/dsaergui.html

- Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act
  http://www.cfsan.fda.gov/~dms/dsaergu2.html

- Who must collect and report to FDA reports of a serious adverse event using MedWatch Form 3500A ?
  http://www.fda.gov/medwatch/getforms.htm

Dietary Supplement Good Manufacturing Regulation:

- Federal Register Dietary supplement Final Good Manufacturing regulation
  http://www.cfsan.fda.gov/~lrd/fr07625a.html

- Dietary Supplement GMP education satellite downlink was held on October 24, 2007. It was very successful with over 70,000 participants world-wide. Slides, Text, and broadcast available at:
  http://www.cfsan.fda.gov/~dms/dscgmps8.html - webcast

Structure Function Notifications:

- Structure function 30 day notification requirements are listed in 21 CFR § 101.93.
- 30 day structure function notifications are available in the FDA dockets office **(docket # 97S-0162)**
- Structure Function Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the FFDCA guidance

New Dietary Ingredient (NDI) Notifications:

- NDI notification requirements are listed in 21 CFR § 190.6.
- NDI notification will be placed on public display at FDA's Documents Management Branch in Docket number 95-S-0316.

FDA Press Office Announcements:

- This takes you to the press announcement page, which includes all safety-related press releases back to 1992.
  http://www.fda.gov/opacom/hpnews.html

Enforcement Actions:

- This is the link to Class 1 recalls and safety alerts (a Class 1 recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences' or death). On the right hand side of this page there is a link to the "archive" which contains all of them back to 1999.
  http://www.fda.gov/opacom/7alerts.html
- This is the link to the weekly enforcement reports which is a compilation of recalls and related actions for all FDA Centers.
  http://www.fda.gov/opacom/Enforce.html