

14. *Economic Report of the President*, Table B-16—Personal Consumption Expenditures, 1959–2001, U.S. Government Printing Office, Washington, DC, February 2002. Obtained data at the Internet site <http://w3.access.gpo.gov/usbudget/fy2003/sheets/b16.xls> on August 14, 2002.

15. "Customer Behavior: How Consumers Shop," *Progressive Grocer*, December 1992, pp. 62–64.

16. "A Shopping for Health Report, 1998: A Look at the Self-Care Movement," *Food Marketing Institute*, Research Department, Washington, DC, and *Prevention Magazine*, Research Department, Emmaus PA, 1998, p. 2.

17. *Consumer Expenditures in 1999*, Report 949, Table A—Average Annual Expenditures of All Consumer Units and Percent Changes, Consumer Expenditure Survey, 1997–99, Bureau of Labor Statistics, U.S. Department of Labor, Washington, DC, May 2001, p. 3. Obtained data from the Internet site <http://stats.bls.gov/cex/csxann99.pdf> on July 25, 2002.

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.4 is amended by revising paragraph (h) to read as follows:

§ 101.4 Food; designation of ingredients.

* * * * *

(h) The common or usual name of a botanical ingredient (including fungi and algae) listed on the label of a dietary supplement must be consistent with the "standardized common name" listed in *Herbs of Commerce, 2nd Edition* (2000) for the plant from which the ingredient is derived. The use of the term "ginseng" as a common or usual name (or part thereof) for any dietary supplement or dietary ingredient is limited to those that are derived from a plant classified within the genus "*Panax*." *Herbs of Commerce, 2nd Edition* (2000) is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this book may be obtained from the American Herbal Products Association, 8484 Georgia Ave., suite 370, Silver Spring, MD 20910, 301–588–1171, FAX: 301–588–1174, e-mail: ahpa@ahpa.org. Copies also may be examined at the

Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(1) The listing of the common or usual name on the label must be followed by statements of:

(i) The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., "Garlic bulb" or "Garlic (bulb)"), except that this designation is not required for algae. The name of the part of the plant must be expressed in English (e.g., "flower" rather than "flos"); and

(ii) The Latin binomial name (i.e., genus and species) of the plant from which the botanical ingredient is derived, stated in parentheses, when no "standardized common name" for the plant is listed in *Herbs of Commerce, 2nd Edition* (2000). In such cases, this Latin binomial name may be listed before the part of the plant and must be stated in accordance with the internationally accepted rules on botanical nomenclature found in the *International Code of Botanical Nomenclature (Saint Louis Code) 2000*. When needed to positively identify the botanical ingredient, the Latin binomial name also must include the author citation (i.e., name(s) of the person(s) who described and published the Latin binomial name in accordance with the internationally accepted rules on botanical nomenclature found in the *International Code of Botanical Nomenclature (Saint Louis Code) 2000*). The *International Code of Botanical Nomenclature (Saint Louis Code) 2000*, a publication of the International Association for Plant Taxonomy, is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this book may be obtained from Koeltz Scientific Books, D-61453 Königstein, Germany; University Bookstore, Southern Illinois University, Carbondale, IL 62901–4422, 618–536–3321, FAX: 618–453–5207, e-mail: [siu@bkstr.com](mailto:suu@bkstr.com); and from Lubrecht & Cramer, 18 East Main St., Port Jervis, NY 12771, 800–920–9334, FAX: 800–920–9334, e-mail: books@lubrechtcramer.com. Copies also may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(2) On labels of single-ingredient dietary supplements that do not include an ingredient list, the identification of the Latin binomial name, when needed, and the part of the plant may be

prominently placed on the principal display panel or information panel, or included in the nutrition label.

Dated: August 14, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–21980 Filed 8–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Etodolac

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of American Cyanamid Co. The supplemental NADA provides for a 500-milligram (mg) tablet size of etodolac for oral use in dogs.

DATES: This rule is effective August 28, 2003.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501, filed a supplement to NADA 141–108 that provides for a 500-mg tablet size of ETOGESIC (etodolac) Tablets used for the management of pain and inflammation associated with osteoarthritis in dogs. The supplemental application is approved as of May 8, 2003, and the regulations are amended in 21 CFR 520.870 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.