



DEPARTMENT OF HEALTH & HUMAN SERVICES

Reviewed & edited.

Public Health Service *gpc*
6/19/91

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
91-DT-25

5/21/91
6-21-91

June 17, 1991

David Decatur, M.D.
President
Decatur Fitness Systems, Inc.
8904 Bash Rd.
Indianapolis, IN 46256

Dear Dr. Decatur:

Inspector Patricia A. Cochran collected a sample of "MEAL IN A BOTTLE DECATUR'S B.L.D. VANILLA CITRUS", net wt. 1.4 oz., lot 1460CB at your firm on October 24, 1990.

Our analysis of this sample revealed it to be in significant violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its enabling regulations, in that it contains significantly more sodium than is declared on the label. Specifically; our analysis found sodium at 209%, 197%, and 195% of the 65 mg declared on the label.

In addition, our review of the label revealed additional deviations, as follows:

1. The principal display panel of the label fails to bear as one of its principal features an appropriately descriptive term that accurately identifies the basic nature of the food or its characterizing properties or ingredients [21 CFR 101.3(b)(3) and 102.5(a)]. The statement of identity also fails to include the particular form of the food such as "drink mix" or beverage base" which is considered to be a necessary part of the statement of identity [21 CFR 101.3(c)].
2. The label statements "Meal in a Bottle", "B.L.D.", "Breakfast . Lunch . Dinner" are false and misleading. [FD&C Act 403(a)(1)].

3. The statement "helps curb your appetite" falsely represents that this food is adequate or effective for this labeled condition [FD&C Act 403(a)(1)].
4. The label statement "Low Fat" may be misleading since this descriptive term has not been defined in the regulations [FD&C Act 403(a)(1)].
5. The claim "high fiber" is false and misleading for a product providing only three (3) grams of fiber. For a "high fiber" declaration to be appropriate, the product would have to contain at least eight (8) grams of fiber.
6. The label statement "supplies more than 100% of the U.S. RDA of XX 7 vital minerals" is false and misleading. [FD&C Act 403(a)(1)].
7. The ingredient statement, nutrition information listing, and firm name and address are not printed in letters at least one-sixteenth inch in height [21 CFR 101.2(c)].
8. The correct headings are "nutrition information" rather than "nutritional information" and "Servings per container" rather than "No. servings" (21 CFR 101.9(c)).
9. The declaration of quantity of contents fails to appear in letters and numerals of not less than 1/8 inch in height (21 CFR 101.105(i)(2)); fails to appear in conspicuous print in distinct contrast (by color) to other matter on the package (21 CFR 101.105(h)); and fails to appear in the ratio of height to width (of the letter) not to exceed a differential of 3 units to 1 unit (not more than 3 times as high as it is wide) (21 CFR 101.105(h)(1)).
10. In the ingredient statement, the ingredient declared as "orange fruit sacs" must be listed by its common or usual name (21 CFR 101.4(a)). The ingredient calcium and sodium caseinate should be listed by a specific name, and not a collective name, in descending order of predominance (21 CFR 101.4(b)).
11. Beta carotene is added as a color but is not so specified.
12. The large Symbol "D" and Decatur Fitness Systems intervenes between the columns of nutrition information.

13. The product contains artificial flavors but the name of the product fails to include the term "artificial" or "artificially flavored" immediately preceding or following the name of the characterizing flavor [21 CFR 101.22(i)].
14. The label makes the statement "Lower Calorie Meal". A food may be labeled as a reduced calorie food only if a comparison of the calorie content of a specified serving of the food with the calorie content of an equivalent serving of the same food without the fabrication or alteration of special dietary significance reveals a calorie reduction of at least one-third [21 CFR 105.66(d)(i)].
15. The specific source of the lecithin must be declared. [21 CFR 101.4(a)].

We note that you were previously advised of most of these labeling violations in a Notice of Adverse Findings letter issued on May 1, 1989.

We recommend that you review your labels for this and other products and that you take immediate action to properly label your food products. It is your responsibility to assure that such products are properly labeled.

Failure to take prompt action may result in regulatory action without further notice. This may include seizure and/or injunction.

Please notify us in writing, within fifteen (15) days of your receipt of this letter, of any actions you have taken, or intend to take, to bring your firm into compliance. Also, we would like to receive a copy of any new or proposed label.

Your response should be directed to this office to the attention of Ms. Judith A. Putz, Compliance Officer.

Sincerely yours,

Carl C. Reynolds
District Director
Detroit District