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Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

June 22, 2000

xc: HFI-35  
DWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 00 - 39

John C. Dowd  
President  
Solocare Pharmaceuticals, Inc.  
1635 West St. Paul Avenue  
Milwaukee, Wisconsin 53233

Dear Mr. Dowd:

This letter is written in reference to your marketing of the products "B-6 & Folic Acid," "B-12 & Folic Acid," "Super High Potency Colostrum," "Esscolloid Red Label," and "Esscolloid Blue Label." Your Internet web site as well as labeling used with these products, including your promotional brochures and the immediate container label for the product "Esscolloid Red Label," include statements or suggestions that these products may be useful in the treatment of various diseases, including the following:

B-6 & Folic Acid: Labeling includes statements suggesting treatment of coronary heart disease, heart disease, reducing the risk of heart attack or death from heart disease and protection from heart disease. Your Internet web site also suggests that this product may be used to protect against cancer, control diabetes and prevent skin disease, cataracts, heart attack and stroke.

B-12 & Folic Acid: Labeling includes statements suggesting treatment of Alzheimer's disease and cognitive disorders, cardiovascular disease, anemia and depression. Your Internet web site also suggests that this product may be used to prevent anemia, heart disease, and Alzheimer's disease and reduce cholesterol.

Colostrum: Labeling includes statements such as treatment of ulcers, promotes healing, and that the product is an antibiotic and antiviral agent. Your Internet web site also suggests that this product repairs nervous system damage, prevents diarrhea, and interferes with gut pathogens.

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Esscolloid Red Label: The immediate container label states that this product may be used in the treatment of other bowel disorders when recommended by a doctor.

Esscolloid Blue Label: Labeling includes a statement that suggests that this product protects against bone fractures and other problems.

Because your Internet web site and labeling include statements which represent or suggest that these products are intended to be used in the cure, mitigation, treatment or prevention of disease, these products are drugs within the meaning of Section 201(g) of the Federal Food, drug and Cosmetic Act (the Act). We are unaware of any evidence that establishes that these drugs are generally recognized as safe and effective for their intended uses. Therefore, these products are new drugs as described in Section 201 (p) of the Act which may not be marketed since no new drug application required by Section 505 of the Act has been approved for any of these drugs.

These drugs are also misbranded within the meaning of Section 502 (a) of the Act because their labeling is false and misleading since they suggest that there is evidence that these drugs are safe and effective for their intended use, when in fact, this has not been established. These drugs are further misbranded within the meaning of Section 502(f)(1) of the Act because their labeling fails to bear adequate directions for their intended uses.

We request that you notify this office in writing within 15 days of receipt of this letter stating the action you will take to discontinue the marketing of these drug products or to otherwise bring them into compliance. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

This letter does not represent a comprehensive review of all of the products distributed by your firm. It also does not represent a complete review of your Internet web site nor all product labeling or promotional materials including immediate container labels, product brochures, product catalogs, newsletters and advertisements. As the president, it is your responsibility to ensure that all products distributed by your firm meet the requirements of the Act and its implementing regulations.

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Your reply should be directed to Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead. Ms. Hoffman may be reached at (612) 334-4100 ext. 159.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

CAH/ccl