



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g1341d
Food and Drug Administration
Pacific Regional Laboratory, Northwest
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Bothell, WA 98021-4421

Telephone: 425-486-8788
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June 4, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUEST**

In reply refer to Warning Letter SEA 01-56

Bruce D. Barlean, President
Barlean's Organic Oils, LLC
4936 Lake Terrell Road
Ferndale, Washington 98248

WARNING LETTER

Dear Mr. Barlean:

We inspected your firm, located at 4936 Lake Terrell Road, Ferndale, Washington, on November 6, 7, and 9, 2000, and found that you have serious violations concerning the marketing of various organic seed oils and encapsulated oil products, in accordance with Sections 505, 502, and 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21 of the Code of Federal Regulations (21 CFR). You can find this Act and 21 CFR on the Internet through links in the FDA's homepage at www.fda.gov.

The products of concern to us include: Barlean's Forti-Flax, Barlean's Flax Oil, Barlean's Flax Oil Capsules, Barlean's Flax Oil (Lignan Rich), Barlean's Flax Oil Capsules (Lignan Rich), Barlean's Omega-Twin, Barlean's Omega-Twin Capsules, Barlean's Omega-Twin (Lignan Rich), Barlean's Omega-Twin Capsules (Lignan Rich), Barlean's The Essential Woman, Barlean's The Essential Woman Capsules, Barlean's Borage Oil, Barlean's Borage Oil Capsules, Barlean's Greens, Barlean's Greens Capsules, Barlean's Omega Twin Flax and Borage Oil Combination, Barlean's Omega Twin Flax and Borage Oil Capsules, Barlean's Lignan Rich Omega Twin Flax and Borage Oil Capsules, and Barlean's Lignan Rich Omega Twin Flax and Borage Oil Combination.

Labeling used with these products, such as your firm's Product Selection Guide, various reprints of The Doctors' Prescription For Healthy Living, various reprints of Health Perspectives, various reprints from Health Counselor, various reprints from Progressive Health Publishing, the Research Report Flaxseed, as well as flyers including Health Benefits of Flax Seed Oil, Health Check, A Quick Guide To Flax, and There's Nothing Fishy About Flaxseed Oil include statements or suggestions that these products may be useful in the treatment of various diseases. These diseases include: AIDS, various cancers, Alzheimer's Disease, cystic fibrosis, diabetes, heart disease, kidney disease, leukemia, lupus, multiple sclerosis, schizophrenia, and stroke. Although you may be marketing these products labeled as dietary supplements or foods, your

labeling includes statements that represent or suggest that these products are intended to be used in the cure, mitigation, treatment or prevention of disease. We are, therefore, concerned with the following violations:

1. By virtue of your labeling, these products are drugs within the meaning of Section 201(g) of the Act. Furthermore, we are unaware of any substantial scientific evidence that demonstrates 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, as required by Section 505 of the Act, has been approved for any of these drugs.
2. These drugs are also misbranded within the meaning of Section 502(a) of the Act because their labeling is false and misleading in that it suggests that there is evidence that these drugs are safe and effective for their intended uses, when, in fact, such evidence has not been established. These products are further misbranded within the meaning of Section 502(f)(1) in that their labeling fails to bear adequate directions for the uses for which they are being offered
3. Your products including: Barlean's Flax Oil Capsules, Barlean's Lignan Rich Flax Oil Capsules, Barlean's The Essential Woman Oil, and Barlean's Forti-Flax are misbranded within the meaning of Section 403(s)(2)(B) and 403(i)(1) in that their labeling fails to include the mandatory statement of identity required for dietary supplements in that they are not labeled as "dietary supplement". For example, "Barlean's Flax Oil Capsule Supplement" may be substituted as an acceptable statement of identity in accordance with 21 CFR 101.3(g).
4. Your products including: Barlean's Flax Oil Capsules, Barlean's Lignan Rich Flax Oil Capsules, Barlean's Flax Oil, Barlean's Lignan Rich Flax Oil, Barlean's Omega Twin Flax and Borage Oil Combination, Barlean's Omega Twin Flax and Borage Oil Capsules, Barlean's Borage Oil Capsules, Barlean's Borage Oil, Barlean's Lignan Rich Omega Twin Flax and Borage Oil Capsules, Barlean's Lignan Rich Omega Twin Flax and Borage Oil Combination, Barlean's Forti-Flax, and Barlean's Greens (both capsules and powder) are misbranded within the meaning of Section 403(r)(1)(A) of the Act and 21 CFR 101.54, because the labels bear one or more of the statements: "potent source of valuable Omega-3 fatty acids", "richest source of omega-3", "lignan rich", lignan fortified", "provides...omega-3, 6, and 9 fatty acids as well as gamma-linolenic acid", "potent source of gamma-linolenic acid", "rich in lignan", "rich in tocotrienols", or "high in omega-3 fatty acids". These statements are unapproved nutrient content claims, because they are unapproved synonyms for authorized content claims and are made for substances for which no Reference Daily Intake (RDI) or Daily Reference Value (DRV) has been established.
5. Your product, Barlean's Forti-Flax, is also misbranded in accordance with Section 403(r)(1)(A) of the Act and 21 CFR 101.54(b). The label bears the statement "high in dietary fiber", however, the product does not meet the eligibility criteria to bear that claim.

Bruce D. Barlean, President
Barlean's Organic Oils, LLC, Ferndale, Washington
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6. The products Barlean's Flax Oil Capsules and Barlean's Lignan Rich Flax Oil Capsules are misbranded with the meaning of Section 403(r)(2)(F) of the Act. The product labels bear the statement: "Twice as much omega-3 as fish oils", which is a percentage claim that is not in accordance with 21 CFR 101.13(q)(3)(ii)(B). Information as to the actual amount of the dietary ingredient in both the food and reference food shall be clearly declared in accordance with 21 CFR 101.13(j)(2)(iv).
7. Your products including: Barlean's Flax Oil Capsules, Barlean's Lignan Rich Flax Oil Capsules, and Barlean's The Essential Woman Oil are misbranded in accordance with Section 403(q)(5)(F) of the Act and 21 CFR 101.36. The supplement facts labels for these products do not meet the requirements of the Act or regulations because nutrition information, which includes the declaration of amounts of omega-3, omega-6, and omega-9 fatty acids along with other ingredients is declared outside of the supplement facts box. In addition, nutrients subject to 21 CFR 101.36(b)(3), which include omega-3 fatty acids and/or flaxseed particulate, are declared in the incorrect portion of the nutrition label in accordance with 21 CFR 101.36(e).
8. The capsule products including: Barlean's Flax Oil Capsules, Barlean's Lignan Rich Flax Oil Capsules, Barlean's Omega Twin Flax & Borage Oil Capsules, Barlean's Borage Oil Capsules, Barlean's Lignan Rich Omega Twin Flax & Borage Oil Capsules, and Barlean's The Essential Woman Capsules are further misbranded within the meaning of Section 403(i)(2) and 21 CFR 101.4. The ingredients: gelatin, glycerin, purified water and carob powder are not declared on product labels.

This letter is not intended to be an all-inclusive list of the deficiencies in your labeling. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. You should further review all of the labeling of your products to assure that they are in compliance. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Pertinent sections of the Act and the regulations are enclosed for your review.

For your information, in addition to product labeling, our review of your Internet web site located at www.barleans.com reveals claims for serious diseases similar to those that are previously referenced in this warning letter.

Please respond within three (3) weeks from receipt of this letter. Your response should outline the specific steps you are taking to correct these violations. We also ask that you explain how you plan to prevent these violations from reoccurring.

Bruce D. Barlean, President
Barlean's Organic Oils, LLC, Ferndale, Washington
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Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any question concerning any issue in this letter, please contact Diane J. Englund at (425) 483-4864.

Sincerely

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR Part 101
Sections 201, 403, 502, and 505 of the Federal Food, Drug, and Cosmetic Act

Cc: WSDA with Disclosure Statement