

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Dr Benedict S Liao Md 7/8/14



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Los Angeles District
19701 Fairchild
Irvine, California
92612-2506
Telephone (949) 608-2900

WARNING LETTER

VIA HAND DELIVERY

July 8, 2014

WL# 25-14

Dr. Benedict Schue-Schie Liao (a.k.a Dr. Wada Masao)
Garfield Medical Group, LLC
Oeyama-Moto Medical Group
Oeyama-Moto Cancer Research Foundation
3106 E. Garvey Avenue South
West Covina, CA 91791

Dear Dr. Benedict Schue-Schie Liao:

This letter is in reference to the inspections of your facility on October 17 through 18, 2012, and between May 28, 2013 and June 4, 2013, by the U.S. Food and Drug Administration (FDA). In addition, we reviewed your website, www.cancertreatmentus.org (website redirects to:

<http://oeyamamotocancerresearchfoundation.org>), and a handout you provide consumers for your marketed product, "Allesgen."¹ Based on our review of the labeling for your "Allesgen" product, we have determined this product is promoted as a drug under Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 *United States Code* (U.S.C.) § 321(g)(1)]. The claims made in the labeling for this product establish that your product is a drug because it is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.

The marketing of your product with these claims violates the Act. Examples of

claims that establish the intended use for “Allesgen” include, but are not limited to, the following:

Article Titles on Your Website Homepage

- “美國最新的發明 . . . 治癒癌末期病人抗癌藥 Allesgen” “American Latest Invention . . . Allesgen Anti-cancer Drug to Cure the Advanced Cancer Patient” (Translated)
- “廖學時醫師研發治癌藥 . . . 超過80人痊癒 . . . 已取得美國及國際專利” “Dr. Schue-Schie Liao Developed Anti-cancer Drug . . . Over 80 People Cured . . . Received U.S. and International Patent” (Translated)

“Allesgen Alternative Treatment” Section on Your Website

Under the Subheading – Action Mechanism:

- “Fibrinolytic effect . . . Anti-platelet aggregation . . . Inhibit tumor cell growth . . . Anti-tumor genesis . . . Anti-De-Differentiation . . . Anti-metastatic [sic] effect”

Under the Subheading – Phase III: Human Volunteer Experiment:

- “Allesgen oral administration to inhibit tumor growth in humans. Allesgen oral administration to late stage cancer patients. . . . All were in their 4th and 6th decades with various types of cancers including breast, lung, colon, ovarian, cervical and uterine origins. All were in either Stage III or Stage IV. (The cancers had metastasized widely either to lung, liver, bladder or rectum). All had been treated with either radiation or chemotherapy after surgery but experience no positive results. . . . we concluded that the treatment of these various represented types of cancers for prolonged periods with ALLESGEN are effective and without side effects.”

You also display labeling in the form of images taken from medical imaging procedures. The descriptions below the images suggest patients with cancer achieved a partial or complete response after treatment with “Allesgen.”

“Allesgen Treatment Information” Handout

- “MAJOR EFFECTS OF THIS MEDICINE ARE . . . Inhibiting growth of tumor cells . . . Inhibiting tumor cells to metastases to host tissues . . . Fibrinolysis . . . Anti-Dedifferentiation; could convert abnormal DNA of tumor cells into normal DNA . . .”
- “What to expect during treatment: It takes at least 3-4 weeks for medicine to take effects. Patient will experience of hot flushes, palpitation, gastric distention, diarrhea (very rare, less than 1%), occasionally, and it takes at least 2.5—3

months for tumor to shrink to 40-50% in size on CT scan findings.”

Based on our review of the labeling for your product, we have determined your product, “Allesgen,” is promoted as a drug as defined by Section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)]. “Allesgen” is also a “new drug” as defined in Section 201(p) of the Act [21 U.S.C. § 321(p)], because it is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. Under Sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an approval of an application filed pursuant to Subsection (b) or (j) is effective with respect to such drug.

We note that “Allesgen” does not meet the requirements governing the use of investigational new drugs under Title 21, *Code of Federal Regulations* (CFR), Part 312, to meet the exemption described in Section 505(i) of the Act [21 U.S.C. § 355(i)]. **(b)(4)**. Under 21 CFR Part 312.40(a)(1), an investigational new drug may only be used in a clinical investigation if the IND has gone into effect as defined in 21 CFR Part 312.40(b). According to official FDA records, your INDs have never gone into effect, and were either cancelled or placed on clinical hold. Therefore, the exemption described under Section 505(i) of the Act does not apply to “Allesgen,” and your sale of “Allesgen” without an approved application violates Sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)].

In addition, “Allesgen” is misbranded under Section 502(a) of the Act [21 U.S.C. § 352(a)], because its labeling is false or misleading. You suggest on your website that FDA is reviewing “Allesgen,” and that FDA has permitted you to begin treating patients while under review. However, as mentioned previously, your INDs have never gone into effect, and FDA has not given you authorization to begin clinical trials. Therefore, your representations are misleading and “Allesgen” is misbranded under Section 502(a) of the Act. The introduction or delivery for introduction into interstate commerce of a misbranded drug violates Section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your product “Allesgen.” You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of

related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Please send your reply to the Food and Drug Administration, Attention:

Dan R. Solis, Director
Import Operations Branch
Los Angeles District
One World Trade Center, Suite 300
Long Beach, CA, 90831

If you have questions regarding any issues in this letter, please contact James R. Miller, Compliance Officer at 562-256-9211.

(b)(4)

A description of the new drug approval process can be found on FDA's website www.fda.gov (<http://www.fda.gov/>). Any questions regarding this process should be directed to the U.S. Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10001 New Hampshire Avenue, Hillandale Building 4th Floor, Silver Spring, MD 20993.

Sincerely,

/S/
Alonza E. Cruse, Director
Los Angeles District

Cc:
Dr. Benedict Schue-Schie Liao (a.k.a Dr. Wada Masao)
Garfield Medical Group, LLC
Oeyama-Moto Medical Group
Oeyama-Moto Cancer Research Foundation
3106 E. Garvey Avenue South
West Covina, CA 91791

Dev GnanaDev, M.D.
The Medical Board of California
2005 Evergreen St, Suite 1200
Sacramento, CA 95815

[1] The website www.cancertreatmentus.com found on the "Allesgen" product label also redirects to <http://oeyamamotocancerresearchfoundation.org/>.

More in 2014

[\(/ICECI/EnforcementActions/WarningLetters/2014/default.htm\)](/ICECI/EnforcementActions/WarningLetters/2014/default.htm)