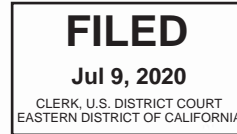


1 McGREGOR W. SCOTT
United States Attorney
2 VINCENTE A. TENNERELLI
ALEXANDRE M. DEMPSEY
3 Assistant United States Attorney
2500 Tulare Street, Suite 4401
4 Fresno, CA 93721
Telephone: (559) 497-4000
5 Facsimile: (559) 497-4099



6 Attorneys for Plaintiff
7 United States of America

8 IN THE UNITED STATES DISTRICT COURT
9 EASTERN DISTRICT OF CALIFORNIA

10
11 UNITED STATES OF AMERICA,
12 Plaintiff,
13 v.
14 HUU TIEU,
15 Defendant.

CASE NO. 1:20-cr-0109 DAD-BAM

18 U.S.C. § 1341 – MAIL FRAUD [TWO
COUNTS]; 21 U.S.C. § 331(a) AND 333(a)(2) –
INTRODUCTION OF MISBRANDED DRUG INTO
INTERSTATE COMMERCE WITH INTENT TO
DEFRAUD OR MISLEAD [THREE COUNTS]; 18
U.S.C. §§ 981(a)(1)(C), 982(a)(7), 21 U.S.C. § 334,
and 28 U.S.C. § 2461(c) - CRIMINAL
FORFEITURE

16
17
18 INDICTMENT

19
20 COUNTS ONE AND TWO: [18 U.S.C. § 1341 – Mail Fraud]

21 The Grand Jury charges:

22 HUU TIEU,
23 defendant herein, as follows:

24 **I. INTRODUCTION**

25 At all relevant times:

26 1. Defendant HUU TIEU (“TIEU”) was a resident of Porterville, California, within the State
27 and Eastern District of California, and was the President and Chief Executive Officer of Golden Sunrise
28 Pharmaceutical, Inc. and Golden Sunrise Nutraceutical, Inc. (collectively, the “Golden Sunrise

1 Companies” or “Golden Sunrise”). He was also the Chief Executive Officer and Chief Financial Officer
2 of EDM Industries, Inc. (“EDM”).

3 2. Golden Sunrise Pharmaceutical, Inc., was registered as a California corporation with the
4 California Secretary of State on or about September 2011. Golden Sunrise Nutraceutical, Inc. was
5 registered as a Delaware corporation with the California Secretary of State on or about March 2018.
6 EDM was registered as a California corporation with the California Secretary of State on or about May
7 2000.

8 3. The Golden Sunrise Companies manufactured, marketed, and sold products that, the
9 companies claimed, effectively treated a variety of medical conditions. EDM manufactured certain
10 products for the Golden Sunrise Companies. The Golden Sunrise Companies were located in Porterville,
11 California, in the State and Eastern District of California. EDM was located in Lindsay, California, in
12 the State and Eastern District of California.

13 4. The United States Food and Drug Administration (“FDA”) was the federal agency
14 responsible for protecting the health and safety of the American public by enforcing the federal Food,
15 Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.* The FDCA was a federal law which, among
16 other things, regulated the manufacture and distribution of foods, drugs, medical devices, and cosmetics.

17 5. One primary purpose of the FDCA was to ensure that drugs sold for use in humans and
18 other animals were safe and effective for their intended uses, and bore labeling containing only truthful
19 and non-misleading information and directions adequate for a layperson to use the drugs safely and for
20 all the purposes for which it was intended. The FDA’s responsibilities under the FDCA included
21 regulating the manufacture, labeling, and distribution of all animal drugs introduced, delivered, and
22 caused to be introduced or delivered in interstate commerce.

23 6. Under the FDCA, the definition of “drugs” included articles intended for use in the
24 diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, 21 U.S.C.
25 § 321(g)(1)(B), and articles (other than food) intended to affect the structure or function of the body of
26 humans, 21 U.S.C. § 321(g)(1)(C). The “intended use” of an article meant the objective intent of the
27 persons legally responsible for the labeling of that article, as determined by such persons’ expressions or
28 the circumstances surrounding the distribution of the article. 21 C.F.R. § 201.128.

1 7. Under the FDCA, a “new drug” was any drug the composition of which was not
2 generally recognized by experts as safe and effective for use under the conditions prescribed,
3 recommended, or suggested in the labeling. 21 U.S.C. § 321(p). With limited exceptions not relevant
4 here, before a new drug could be lawfully shipped in interstate commerce, its sponsor (usually the
5 manufacturer) had to first obtain FDA approval of a New Drug Application (“NDA”) for that drug. 21
6 U.S.C. § 355(a). In order to obtain FDA approval for an NDA, the sponsor of the NDA had to
7 demonstrate to the FDA’s satisfaction that, among other things, its new drug was safe and effective for
8 its intended uses. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50.

9 8. Under the FDCA, a “prescription drug” was any drug intended for use in humans that,
10 because of its toxicity or potential for harmful effect, the method of its use, or the collateral measures
11 necessary for its use, was not safe for use except under the supervision of a practitioner licensed by law
12 to administer such drug; or a drug which was limited by an approved application under 21 U.S.C. § 355
13 for use under the professional supervision of a practitioner licensed by law to administer such drugs. 21
14 U.S.C. § 353(b)(1).

15 9. The FDCA defined “label” as a display of written, printed, or graphic matter upon the
16 immediate container of any article, including food and drugs. 21 U.S.C. § 321(k). “Labeling” was a
17 broader term, and was defined as “all labels and other written, printed, or graphic matter upon any article
18 or any of its containers or wrappers, or accompanying such article.” 21 U.S.C. § 321(m). Written,
19 printed or graphic matter on internet websites operated by the persons that manufactured or distributed
20 an article, or from which one could purchase an article, or linked to a website from which one could
21 purchase an article, could be labeling for that article.

22 10. Under the FDCA, a drug was deemed to be misbranded for any of a number of reasons.
23 Relevant to this indictment, a drug was misbranded :

- 24 a) If its labeling was false or misleading in any particular. 21 U.S.C. § 352(a)(1).
25 b) Unless its labeling bore adequate directions for use. 21 U.S.C. § 352(f)(1). “Adequate
26 directions for use” was defined as directions under which a layman could use a drug safely and
27 for the purposes for which it was intended. 21 C.F.R. § 201.5. Because prescription drugs, by
28 definition, can only be used safely, if at all, at the direction, and under the supervision, of a

1 physician, directions could not be written under which a layperson could use a prescription drug
2 safely.

3 11. At all times relevant to this Indictment, the FDCA prohibited causing the introduction or
4 delivery for introduction into interstate commerce of misbranded drugs. 21 U.S.C. § 331(a).

5 12. Under certain conditions, a drug was eligible for a “regenerative medicine advanced
6 therapy” (RMAT) designation by the FDA if it was a cell therapy, therapeutic tissue engineering
7 product, human cell and tissue product, or any combination product using such therapies or products; it
8 was intended to treat, modify, reverse, or cure a specific serious or life-threatening disease or condition;
9 and preliminary clinical evidence indicated that the drug had the potential to address unmet medical
10 needs for such disease or condition. 21 U.S.C. § 356g, the FDA had the sole authority to designate
11 regenerative medicine therapy drugs. To obtain an RMAT designation, the drug sponsor had to first
12 request the FDA to grant this designation and await FDA’s decision.

13 13. Cellular therapy (“CT”) products included cellular immunotherapies, cancer vaccines,
14 and other types of cells (including stem cells) for certain therapeutic indications, as well as the practice
15 of injecting humans with foreign proteins like the placenta or lungs of unborn lambs.

16 14. The Medicare program was a Federal health care program established by the Social
17 Security Act of 1965 to provide medical services to aged, blind, and disabled individuals who qualified
18 under the Social Security Act. The United States Department of Health and Human Services, through its
19 agency, the Centers for Medicare & Medicaid Services, administered Medicare. Medicare had federally-
20 funded programs that paid for medically necessary services and prescription drug benefits for eligible
21 beneficiaries.

22 15. The Medicaid program was a Federal health care program authorized by Title XIX of the
23 Social Security Act. 42 U.S.C. §§ 1396 *et seq.* Medicaid was a joint federal-state program that provided
24 health care benefits, including coverage of medical office visits and prescription drugs, for certain
25 groups including the poor and disabled. The California Medicaid program was also known as “Medi-
26 Cal.”

27 16. UnitedHealthcare of California (“UHC”) provided medical insurance to certain California
28 residents and reimbursed health care providers, pharmacies, and other providers for qualifying goods

1 and services provided to UHC beneficiaries.

2 17. The Healthcare Common Procedure Coding System (“HCPCS”) was a standardized
3 coding system used to identify certain supplies, services, and products provided to a given patient.
4 Billing providers used HCPCS on health insurance reimbursement claim forms to indicate the specific
5 good or service for which they are requesting reimbursement. M0075 was the HCPCS code for cellular
6 therapy.

7 **II. THE SCHEME TO DEFRAUD**

8 18. From a date unknown but no later than on or about February 4, 2020, through on or about
9 July 9, 2020, in the State and Eastern District of California and elsewhere, defendant TIEU, with the
10 intent to defraud, knowingly devised and intended to devise a scheme and artifice to defraud insurers
11 including UHC, Medicare, and Medi-Cal, of money and property and to obtain money and property
12 from customers and insurers, including UHC, Medicare, and Medi-Cal, by means of materially false and
13 fraudulent pretenses, representations, and promises.

14 **III. MANNER AND MEANS**

15 19. The scheme to defraud was carried out, in substance, generally through the following
16 manner and means, among others:

17 20. Defendant TIEU, with the intent to defraud, submitted and intended to submit false and
18 fraudulent claims for reimbursement to UHC, Medicare, and Medi-Cal representing that beneficiaries
19 had received cellular therapy from Golden Sunrise when, in fact, they had not.

20 21. TIEU devised this scheme and artifice to defraud for the purpose of receiving money and
21 property in the form of claim reimbursements from the insurers. In addition to distributing products at
22 Golden Sunrise and seeking reimbursement from insurers, TIEU also provided products to S.H., the
23 Golden Sunrise Companies’ “Education Director,” so she could sell them at her own business,
24 F.H.E.L.M. TIEU’s scheme to defraud also included conveying false information regarding Golden
25 Sunrise products so that customers would purchase them from S.H.

26 **A. False Statements about Golden Sunrise Products to Obtain Beneficiaries’ Medical
27 Insurance Information**

28 22. Beginning at least on or about March 23, 2020, TIEU caused false statements to be made

1 to members of the media, to potential customers of Golden Sunrise, and to the general public that
2 Golden Sunrise products were FDA approved for the specific indication of treating the disease the
3 World Health Organization has named COVID-19, which stands for coronavirus disease of 2019 and is
4 caused by SARS-CoV-2, which stands for severe acute respiratory syndrome coronavirus 2. Among
5 other means, TIEU caused these false statements to be made through electronic mail, the Golden Sunrise
6 Companies' websites, posts on a social media platform, and verbal and written representations to
7 potential customers and the public. TIEU made these misrepresentations in part to induce customers to
8 provide their medical insurance information, which he intended to use and caused to be used in
9 furtherance of the scheme to defraud.

10 23. At all relevant times, the Golden Sunrise Companies marketed and sold products that,
11 when combined, were represented to constitute various "plans of care" and purportedly treated a variety
12 of medical conditions. For example, "ImunStem" was a product marketed and sold by the Golden
13 Sunrise Companies and was manufactured by EDM. The claimed ingredients of ImunStem, according to
14 the Golden Sunrise Companies, were olive leaf, yarrow, rosemary, yucca, and cassia oil. ImunStem was
15 variously marketed through website claims, emails, and printed material sent with the product to
16 customers as being intended to treat HIV, cancer, Hepatitis, and COVID-19.

17 24. When a customer with insurance, including insurance through UHC, Medicare, or Medi-
18 Cal, acquired Golden Sunrise products from the Golden Sunrise Companies, TIEU and others acting at
19 his direction obtained the customer's insurance information and submitted and caused to be submitted a
20 reimbursement claim to the customer's insurer by U.S. Mail, other common carriers, and by electronic
21 means. In furtherance of the scheme to defraud and in part to induce customers to provide their medical
22 insurance information, TIEU provided products to customers in person and, for patients and
23 practitioners residing outside the Porterville, California area, mailed and caused to be mailed Golden
24 Sunrise products by U.S. Mail and other common carriers.

25 25. At a date unknown to the grand jury but no later than on or about March 23, 2020, TIEU
26 began promoting ImunStem as a treatment for COVID-19. On or about March 23, 2020 TIEU sent an
27 email to J.M., with an attachment titled "Letter to Media." The attachment was a letter describing
28 Golden Sunrise products and made the following false and fraudulent statements, which TIEU knew to

1 be false and fraudulent:

2 a) “In this time of great emergency in our country, it is urgent to raise the awareness
3 of the availability of a product, ImunStem, which has already been screened and approved by the
4 United States Food and Drug Administration (FDA) for the COVID-19 virus. It is an alternative
5 medicine approved by the FDA. This was accomplished under their new Department of
6 Regenerative Advanced Therapy formed in February 2017. This department was created to
7 screen and evaluate the emergence on the market of these types of products. The 2016 Cures Act,
8 passed by the 114th United States Congress, established the criteria for these regenerative drugs /
9 medicinals. These medicinals must be able to regenerate our cells 1) at a cellular level, 2) they
10 can treat, modify, reverse or cure Serious or Life-threatening conditions, and 3) they have the
11 potential to address unmet medical needs for such conditions. ImunStem, an herbal product,
12 produced by Golden Sunrise Nutraceutical, met these strict criteria.”

13 b) “[Imunstem] became the first and only dietary supplement, unlike any other
14 dietary supplement on the market, to be qualified as a prescription drug human medicine by the
15 FDA in July 02, 2018 In order for ImunStem to qualify as a prescription medicine, it had to
16 meet the very arduous testing that the FDA requires for all prescription drugs, even though it was
17 not a drug.”

18 c) “The FDA established [Imunstem] as safe and effective to treat, modify, reverse,
19 or cure Serious or Life-threatening conditions, such as hypertension, cancer, fibromyalgia,
20 Lyme’s disease, and in this case, the COVID-19 virus.”

21 d) “Lastly, but crucially important, is the fact that the FDA has not only approved
22 the ImunStem herbal dietary supplement, but all of the herbal products and treatments produced
23 thus far by Golden Sunrise Nutraceutical. When the FDA physically came to Golden Sunrise
24 Nutraceutical’s location in March 2019, they inspected all of the therapies, claims, and
25 production. They found Golden Sunrise Nutraceutical dietary supplements to be legitimate and
26 valid to treat, modify, or reverse Serious or Life-threatening conditions and illnesses. Unlike
27 other businesses that have been forced to close their business or drop claims on their web site,
28 the FDA approved the web site and the therapies developed by Golden Sunrise Nutraceutical to

1 rejuvenate and transform our cells.”

2 26. As TIEU was aware, contrary to these statements, no Golden Sunrise product, including
3 Imunstem, had ever been approved by the FDA for any purpose. No drug by any manufacturer had been
4 approved by the FDA to treat COVID-19. ImunStem did not receive an RMAT designation from the
5 FDA. In 2017, the FDA expressly informed TIEU that ImunStem did not qualify for an RMAT
6 designation. On or about November 15, 2018, the FDA’s Electronic Drug Registration and Listing staff
7 informed TIEU, by email, that ImunStem “was never approved.” On or about September 16, 2019, the
8 FDA’s Center for Drug Evaluation and Research reminded TIEU that ImunStem had been rejected for
9 an RMAT designation in 2017, “was not approved by the FDA,” and was not cell therapy.

10 27. Additionally, ImunStem did not meet FDA testing requirements for prescription drugs,
11 and the FDA did not establish ImunStem as safe and effective for treating any condition. An FDA
12 inspector did conduct an on-site inspection of Golden Sunrise in 2019. However, he did not make any
13 finding that any Golden Sunrise product was legitimate or valid to treat any condition. The inspector did
14 not approve the Golden Sunrise Companies’ websites. In fact, he addressed, with TIEU, the false claim
15 on a website TIEU managed, ImunStem.com, that ImunStem was FDA approved, leading TIEU to
16 remove the claim from the website. TIEU knew each of these facts when he sent the letter to J.M.

17 28. In furtherance of the scheme to defraud and to recruit additional customers from whom
18 he could obtain medical insurance information, TIEU caused J.M. to send the “Letter to Media”
19 document by email, between on or about March 24, 2020 to on or about March 31, 2020, to various
20 media outlets with the subject line “FDA Approved Alternative Medicine for COVID – 19.” J.M. carbon
21 copied TIEU on each email. The domain names of the recipients of the emails included cbs.com,
22 foxtv.com, bos.lacounty.gov (the Los Angeles County Board of Supervisors), nytimes.com, ktl.com,
23 msnbc.com, and cnn.com.

24 29. Also in furtherance of the scheme to defraud and to recruit additional customers, at a date
25 unknown to the grand jury but no later than April 25, 2020, TIEU began marketing a plan of care called
26 the “Emergency D-Virus Plan of Care” that purportedly treated COVID-19. TIEU marketed the plan of
27 care as a box containing the Golden Sunrise products “AnterFerron-1, AnterFerron-2, ImunStem, and
28 Aktiffvate.” Like ImunStem, the main ingredients of Anterferron-1, AnterFerron-2, and Aktiffvate were

1 herbal, including “Bilberry leaf,” “Mistletoe,” and “Eucalyptus extract.

2 30. In furtherance of the scheme to defraud, TIEU placed, and caused to be placed, a banner
3 at the top of the Golden Sunrise Companies’ websites that read “NEW COVID-19 TREATMENT
4 EMERGENCY D-Virus Plan Care.” If the internet user clicked on the banner, the website would
5 redirect to a .pdf file (the “Emergency D-Virus Pdf”), which TIEU had uploaded and caused to be
6 uploaded, that contained the following false and fraudulent representations regarding the Emergency D-
7 Virus Plan of Care:

8 a) “Patients with late stages of Hepatitis C, and AIDS / HIV have responded with
9 greatly improved quality-of-life and extending their lives when treated with ImunStem and
10 Aktiffvate. For viral colds, Aktiffvate, when given in frequent dosing, as frequent as every one
11 half (½) hour to one (1) hour, will not only alleviate the symptoms quickly, but stop the cold
12 virus itself, usually in less than 2 – 3 days. Now AnterFeerons has been added to the ImunStem
13 and Aktiffvate and shown added improvement for a variety of infections associated with cancer
14 patients and the chronically ill, whether it be viral or bacterial.”

15 b) “Golden Sunrise Nutraceutical metabolic therapies will treat Serious or Life-
16 threatening conditions.”

17 c) “ImunStem, Aktiffvate, and AnterFeerons herbs are the basis of the whole cellular
18 therapy developed by Golden Sunrise Nutraceutical. They have proven themselves to the United
19 States Food & Drug Administration (FDA).”

20 d) “ImunStem, an herbal product, was the first dietary supplement in the United
21 States to be approved as a prescription medicine and also for the indication to treat Serious or
22 Life-threatening conditions. It qualified for both of these under the Regenerative Medicine
23 Advance Therapy (RMAT) designation in the 2016 Cures Act, enacted by the 114th United States
24 Congress. This designation acknowledges not only the effectiveness of these herbs, usually only
25 associated with pharmaceutical drugs, but also causing no side effects, a quality of dietary
26 supplements.” Golden Sunrise products, including Imunstem, are “uniquely qualified to treat and
27 modify the course of the Coronavirus epidemic in CHINA and other countries.”

28 31. TIEU caused these false statements and misrepresentations to be made despite knowing

1 that the FDA had never approved any Golden Sunrise Company product, no Golden Sunrise product had
2 received an RMAT designation or qualified for an RMAT designation, no Golden Sunrise Product was a
3 “cellular therapy,” and that ImunStem had not been FDA approved for any intended use, including the
4 treatment of COVID-19.

5 32. On or about April 29, 2020, the Federal Trade Commission (“FTC”) ordered TIEU to
6 cease and desist from advertising and claiming that the Golden Sunrise products could cure and treat
7 COVID-19 or other diseases.

8 33. On or about May 8, 2020, TIEU met with an undercover investigator at the Golden
9 Sunrise Nutraceutical, Inc. office at 219 North E Street, Porterville, California. When the undercover
10 investigator asked if she should take her 68-year-old mother, whom she told TIEU had COVID-19 and
11 symptoms that included shortness of breath, to the hospital, TIEU responded, in part, “No. You cannot
12 go in there,” as he claimed Golden Sunrise had the only treatment for COVID-19.

13 34. In addition to marketing and selling Golden Sunrise products from the Golden Sunrise
14 Nutraceutical, Inc. office, TIEU also supplied Golden Sunrise products, including the Emergency D-
15 Virus Plan of Care, to S.H. for S.H. to resell at her business, F.H.E.L.M, in Porterville, California. For
16 example, on or about May 15, 2020, an undercover investigator met with S.H. at F.H.E.L.M. The
17 investigator purchased ten doses of ImunStem and ten doses of another Golden Sunrise product,
18 Aktiffvate. The investigator paid S.H. for the products in cash.

19 35. On or about June 19, 2020, TIEU told an undercover agent with the Federal Bureau of
20 Investigation, posing as a potential Golden Sunrise customer, that the customer would not have to pay
21 for the Emergency D-Virus Plan of Care because the treatment would be reimbursed by “the
22 government.” TIEU also mentioned billing insurance for the Plan of Care product. TIEU further falsely
23 told the undercover agent that the Emergency D-Virus Plan of Care was FDA approved.

24 36. At all relevant times, TIEU caused the above misrepresentations to be made, in part, to
25 obtain medical information from customers for use in furtherance of the scheme to submit false and
26 fraudulent claims to insurers.

27 **B. False Statements to Insurers**

28 37. In addition to convincing customers, including patients and practitioners, to purchase

1 Golden Sunrise products through false and fraudulent statements, TIEU's scheme also involved
2 submitting false claims for reimbursement to customers' insurers.

3 38. TIEU submitted and caused to be submitted claims for reimbursement by mail, other
4 common carriers, and by electronic means using a standard CMS Form 1500 claim form. This form
5 requires the billing provider to input, among other information, the patient's name, personal information,
6 insurance information, the dates of service, the provider who rendered services, the reimbursement
7 amount the provider is seeking in a column titled "\$ CHARGES," and the specific services the patient
8 received by billing code, including HCPCS code, in a column titled "PROCEDURES, SERVICES, OR
9 SUPPLIES." As a general matter, insurers use the billing codes listed on submitted Forms 1500 to
10 determine whether the service rendered is reimbursable and, if so, the reimbursement amount.

11 39. The claims TIEU submitted and caused to be submitted were false because TIEU billed
12 HCPCS code M0075 for cellular therapy despite knowing that no Golden Sunrise customer had received
13 cellular therapy. For example, on or about May 4, 2020, TIEU submitted and caused to be submitted
14 three reimbursement claims to UHC for customers who received the Emergency D-Virus Plan of Care.
15 Under the column for "\$ CHARGES" on each claim, TIEU input and caused to be input "\$170,000" on
16 two of the claims and "\$23,000" on the third claim. Each claim contained the following false
17 information:

- 18 a) Under "PROCEDURES, SERVICES, OR SUPPLIES," the form states "M0075,"
19 the HCPCS code for cellular therapy.
20 b) On the top left corner of the form, in large bolded letters, the form states "Cellular
21 Therapy."

22 **IV. USE OF THE MAILS**

23 40. On or about the dates listed below, within the State and Eastern District of California, and
24 elsewhere, for the purpose of carrying out and executing the scheme and artifice to defraud customers
25 and to obtain funds from customers and insurers, including UHC, Medicare, and Medi-Cal, as more
26 fully set forth above, and attempting to do so, TIEU caused the mail matter described below to be placed
27 in a post office or an authorized depository for mail matter, to be sent and delivered by the United States
28 Postal Service, and knowingly caused to be delivered by mail according to the direction thereon:

COUNT	APPROXIMATE DATE OF MAILING	DESCRIPTION
ONE	April 30, 2020	Package containing Golden Sunrise Nutraceutical, Inc. products, mailed from Porterville, California to patient S.C. in West Covina, California, by United States Mail.
TWO	July 7, 2020	Package containing Golden Sunrise Nutraceutical, Inc. products, mailed from Porterville, California to undercover FDA agent purporting to be health care provider in Kirkland, Washington

All in violation of Title 18, United States Code, Section 1341.

COUNTS THREE THROUGH FIVE: [21 U.S.C. §§ 331(a) and 333(a)(2)– Introduction of Misbranded Drug Into Interstate Commerce with Intent to Defraud or Mislead]

The Grand Jury further charges:

HUU TIEU,

defendant herein, as follows:

41. Paragraphs 1 through 17 and 19 through 40 are hereby re-alleged and incorporated as though set forth in full herein.

42. Beginning on a date unknown to the grand jury but no later than March 30, 2020, TIEU began mailing the Emergency D-Virus Plan of Care, which consisted of a box containing various vials of Golden Sunrise products including ImunStem, to various practitioners, public officials, and other individuals both inside and outside the State and Eastern District of California. The boxes TIEU mailed also contained a paper copy of the Emergency D-Virus Pdf, including the misrepresentations described in paragraph 27 hereof. These shipments included shipments to public officials outside of California that attached a letter containing the following false statement: “These products have been approved by the Food and Drug Administration (FDA), and are listed in the “Regenerative Advance Therapy Designation.” TIEU delivered the boxes into interstate commerce by mailing them by United States Mail from Porterville, California to various destinations outside of California. These shipments were mislabeled due to misrepresentations in the shipments themselves and misrepresentations TIEU made and caused to be made on the Golden Sunrise websites, by electronic mail, on social media, through in-

1 person and telephone communications, and through other means.

2 43. In addition to containing false and misleading labeling, the ImunStem contained in the
3 Emergency D-Virus Plan of Care was also misbranded because it was a prescription drug that lacked
4 adequate labeling. The Emergency D-Virus Pdf stated, “ADMINISTRATION OF IMUNSTEM,
5 AKTIFFVATE, ANTERFEERON-1, and ANTERFEERON-2, SHOULD ALWAYS BE UNDER THE
6 SUPERVISION OF A PHYSICIAN. RECOMMENDATION FOR GOLDEN SUNRISE
7 NUTRACEUTICAL EMERGENCY D-VIRUS PLAN OF CARE IS BASED ON MEDICAL
8 EVALUATION OF THE PATIENT.” It also stated that ImunStem “was the first dietary supplement in
9 the United States to be approved as a prescription medicine.” As a prescription drug, the ImunStem
10 contained in the Emergency D-Virus Plan of Care could not be adequately labeled and, accordingly, was
11 mislabeled when shipped by TIEU.

12 44. The ImunStem, among other articles contained in the “Emergency D-Virus Plan of Care”
13 was a “drug” as defined above because its intended use, as expressed in the labeling of the product and
14 in TIEU’s and others’ representations elsewhere, was the treatment of “Serious or Life-threatening
15 [Medical] Conditions,” including COVID-19.

16 45. On or about the dates set forth below, in the State and Eastern District of California and
17 elsewhere, defendant HUU TIEU did, with the intent to defraud and mislead, introduce and deliver for
18 introduction into interstate commerce and cause to be introduced and delivered for introduction into
19 interstate commerce in Porterville, California, a drug, ImunStem, that was misbranded within the
20 meaning of 21 U.S.C. § 352(a)(1) and (f)(1) in that the labeling of the drug was false and misleading and
21 inadequate as previously described.

COUNT	APPROXIMATE DATE OF DELIVERY INTO INTERSTATE COMMERCE	MANNER OF DELIVERY	DRUG DELIVERED INTO INTERSTATE COMMERCE	LOCATION TO WHICH DRUG WAS MAILED
THREE	March 30, 2020	U.S. Mail	ImunStem	2 Woodward Ave., Suite 1126 Detroit, Michigan 48209
FOUR	March 30, 2020	U.S. Mail	ImunStem	P.O. Box 30013, Lansing, Michigan 48909
FIVE	July 7, 2020	U.S. Mail	ImunStem	9805 NE 116 th Street #7353 Kirkland, WA 98034

All in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

FORFEITURE ALLEGATION: [18 U.S.C. §§ 981(a)(1)(C), 982(a)(7), 21 U.S.C. § 334, and 28 U.S.C. § 2461(c) - Criminal Forfeiture]

23. Upon conviction of the offense alleged in Count One of this Indictment, the defendant shall forfeit to the United States, pursuant to Title 18, United States Code, Section 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, that constitutes or is derived from proceeds traceable to a violation of the offense.

24. Upon conviction of the offenses alleged in Counts Two through Five of this Indictment, the defendant shall forfeit to the United States, pursuant to Title 18, United States Code, Section 982(a)(7), property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

25. Upon conviction of the offenses alleged in Counts Three through Five of this Indictment, the defendant shall forfeit to the United States, pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c), any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale after shipment

1 in interstate commerce, and any drug that is a counterfeit drug, any container of a counterfeit drug, any
2 punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a
3 counterfeit drug or drugs, and any adulterated or misbranded device as a result of such offenses.

4 26. If any of the property described above, as a result of any act or omission of the defendant:

- 5 a. cannot be located upon the exercise of due diligence;
6 b. has been transferred or sold to, or deposited with, a third party;
7 c. has been placed beyond the jurisdiction of the court;
8 d. has been substantially diminished in value; or
9 e. has been commingled with other property which cannot be divided without
10 difficulty,

11 the United States of America shall be entitled to forfeiture of any other property of the defendant, up to
12 the value of the property subject to forfeiture, including but not limited to a personal forfeiture money
13 judgment, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United
14 States Code, Section 982(b), and 28 U.S.C. § 2461(c).

15
16 A TRUE BILL.

17 **/s/ Signature on file w/AUSA**

18
19 _____
20 FOREPERSON

21 
22 _____
23 MCGREGOR W. SCOTT
24 United States Attorney
25
26
27
28

No. _____

1:20-cr-00109-DAD-BAM

UNITED STATES DISTRICT COURT

Eastern District of California

Criminal Division

THE UNITED STATES OF AMERICA

vs.

HUU TIEU

INDICTMENT

VIOLATION(S): 18 U.S.C. § 1341 – Mail Fraud [Two Counts]; 21 U.S.C. § 331(a) and 333(a)(2) – Introduction of Misbranded Drug into Interstate Commerce with Intent to Defraud or Mislead [Three Counts]; 18 U.S.C. §§ 981(a)(1)(c), 982(a)(7), 21 U.S.C. § 334, and 28 U.S.C. § 2461(c) - Criminal Forfeiture

A true bill,

/s/ Signature on file w/AUSA

Foreman.

Filed in open court this _____ 9th _____ day

of _____ July _____, A.D. 20 20 _____

Clerk
/s/ Judy Streeter

Bail, **No Bail Warrant Pending Hearing**

Carol H. Delaney

United States v. HUU TIEU
Penalties for Indictment

Defendant
HUU TIEU

COUNTS 1-2: **HUU TIEU**

VIOLATION: 18 U.S.C. § 1341 – Mail Fraud

PENALTIES: Statutory maximum of 20 years in prison
Fine of up to \$250,000, or both fine and imprisonment
Supervised release of up to 3 years

SPECIAL ASSESSMENT: \$100 (mandatory on each count)

COUNTS 3-5: **HUU TIEU**

VIOLATION: 21 U.S.C. §§ 331(a) and 333(a)(2) – Introduction of Misbranded Drug into
Interstate Commerce with Intent to Defraud or Mislead

PENALTIES: Statutory maximum of 3 years in prison
Fine of up to \$10,000 or both fine and imprisonment
Supervised release of up to 1 year

SPECIAL ASSESSMENT: \$100 (mandatory on each count)

FORFEITURE ALLEGATION: **HUU TIEU**

VIOLATION: 18 U.S.C. §§ 981(a)(1)(C), 982(a)(7), 21 U.S.C. § 334, and
28 U.S.C. § 2461(c)

PENALTIES: As stated in the charging document