A.I.G Technologies, Inc. 12/5/17

U.S. FOOD & DRUG ADMINISTRATION

Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204

December 5, 2017

CMS Case # 490872

WARNING LETTER

VIA UPS EXPRESS

Stephen H. Dawes, Owner
AIG Technologies, Inc.
5001 NW 13th Ave, Suite B
Deerfield Beach, FL 33064

Dear Mr. Dawes:

From September 29, 2015 through November 17, 2015, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, located at 5001 NW 13th Ave, Suite B, Deerfield Beach, Florida. Our investigators found that you are a contract manufacturer of over-the-counter (OTC) and prescription drug products. Based on the information collected during the inspection, we have determined that you manufacture unapproved and misbranded new drugs in violation of sections 301(a) and (d), and 505(a) of the FD&C Act [21 U.S.C. §§ 331(a) and (d), and 355(a)].

We acknowledge your written response to the FDA Form 483 dated December 2, 2015. Due to the lack of supporting documentation, we are unable to verify the adequacy of the corrective actions.

The significant violations documented include, but are not limited to, the following:

A. Unapproved New Drug Violations

1. Products Marketed as Prescription Drugs

Based on the information collected during the recent inspection, you manufacture, label and pack unapproved new drugs in violation of sections 301(d) and 505(a) of the FD&C Act.

The prescription unapproved new drugs include, but are not limited to:

- Sodium Sulfacetamide 10% and Sulfur 5% Lotion (NDC 44523-607), which is indicated "for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis";
- Sodium Sulfacetamide 10% and Sulfur 5% Emollient Cream (NDC 44523-603), which is indicated "for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis";
- Sodium Sulfacetamide 10% and Sulfur 5% Suspension (NDC 44523-604), which is indicated "for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis";
- 45% Urea Nail Gel (NDC 51862-181), which is indicated "for use in the topical treatment for debridement and promotion of normal healing of hyperkeratotic surface lesions, particularly where healing is retarded by local infection, necrotic tissue, fibrinous or purulent debris or eschar";
- Utopic Cream (Urea 41%) (NDC 57893-301), which is indicated for "the treatment of hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratosis and calluses"; and
- Formaldehyde 10% (NDC 49908-167), which is indicated as a "drying agent for pre and post-surgical removal of warts, or for non-surgical laser treatment of warts where dryness is required. Safeguards against offensive odor and dries excessive moisture of feet."

The above products are drugs within the meaning of section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)], because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. Further, as labeled, these drugs are "new drugs" within the meaning of section 201(p) of the FD&C Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in the labeled uses.

Under sections 301(d) and 505(a) of the FD&C Act, a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the FD&C Act [21 U.S.C. § 355(b) or (j)] is in effect for the drug. There are no FDA-approved applications on file for the drugs listed above. The marketing of these drugs, or other new drugs, without an approved application constitutes a violation of these provisions of the FD&C Act.

2. Products Marketed as OTC Drugs

The Derma Numb Tattoo Anesthetic Spray labeling includes the following claims that demonstrate the intended uses of this product. This list is not inclusive of all claims demonstrating the product's intended use.

Statements that appear on the product label:

- "temporarily relieves pain from tattoo procedures"
- "FDA REGISTERED"
- "For Professional Use Only."

Based upon the above claims, Derma Numb Tattoo Anesthetic Spray is a drug within the meaning of section 201(g)(1)(B) of the FD&C Act because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act because it is intended to affect the structure or function of the body. Specifically, it is intended for use as an external analgesic.

Drug products intended for external analgesic indications such as the relief of pain are being evaluated under the developing monograph for Over-the-Counter (OTC) External Analgesics (48 FR 5852, February 8, 1983). Pending the promulgation of a final monograph, the agency generally does not intend to object to the marketing of products that meet both the proposed formulation and labeling conditions outlined in the tentative final monograph ("TFM") unless a particular product poses a public health concern. Such marketing, however, is subject to the risk that a final rule may require reformulation and/or relabeling or FDA approval through the "new drug" procedures of the FD&C Act (Section 505).

Derma Numb Tattoo Anesthetic Spray is not labeled in accordance with the TFM for OTC External Analgesics. While lidocaine, the labeled active ingredient, is an active ingredient included in the TFM, the proposed indications for which lidocaine has been tentatively found to be generally recognized as safe and effective "GRAS/E" in the TFM are limited to the temporary relief of pain and/or itching, which can be followed by "associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and/or minor skin irritations" (48 FR 5852 at 5868). Lidocaine is not proposed to be GRAS/E for indications related to tattooing under the TFM, and, due to the nature of the injury to the skin caused during the tattooing procedure, use of lidocaine for this indication as directed in the Derma Numb labeling raises safety concerns relating to the potential for adverse events due to the systemic absorption of the active ingredient. The proposed GRAS/E determination for lidocaine in the TFM for OTC external analgesics is therefore inapplicable to this product. Furthermore, we are not aware of any adequate and well controlled clinical trials in the published literature that support a determination that Derma Numb Tattoo Anesthetic Spray marketed by A.I.G. or Atlas Tat, is GRAS/E for its labeled indications.

Derma Numb Tattoo Anesthetic Spray, as labeled, is therefore a "new drug" within the meaning of section 201(p) of the FD&C Act because it is not generally recognized among scientific experts as safe and effective for the drug uses described in its labeling. "New drugs" may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FD&C Act is in effect for the drug. Derma Numb Tattoo Anesthetic Spray is not the subject of an approved new drug application; therefore, marketing this product in the United States is prohibited under section 301(d) of the FD&C Act and violates section 505 the FD&C Act.

B. Misbranding Violations

1. Products Marketed as Prescription Drugs

The above products in Section A.1. of this letter also are "prescription drugs" as defined in section 503(b)(1)(A) of the FD&C Act because these drugs are not safe for use except under the supervision of a practitioner licensed by law to administer them.

Because these prescription drug products are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use them safely for their intended uses. Consequently, the labeling of your firm's unapproved prescription drug products fail to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(l) of the FD&C Act. Because your drugs lack the required FDA approved applications, they are not exempt under 21 CFR 201.115 from the requirements of section 502(f)(1) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of these drugs, therefore, violates sections 301(a) of the FD&C Act.

C. Conclusion

Violations cited in this letter are not intended as an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating the violations identified above, determining their causes, preventing

their recurrence, and preventing other violations.

You should take prompt action to review all of your products and their associated labeling for claims that may be in violation of the Act. It is your responsibility to assure that your firm complies with all requirements of the FD&C Act and its implementing 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. You should discontinue manufacturing and distributing all of your firms' unapproved new drugs immediately.

Within 15 working days of receipt of this letter, please notify this office, in writing, of the specific steps that you have taken to correct and prevent the recurrence of violations. Include an explanation of each step being taken to prevent the recurrence of violations and copies of the related documentation. If you cannot complete corrective actions within 15 working days, state the reasons for the delay and the date by which you will have completed the corrections.

All firms are required to electronically update the listing of their products under section 510(j) of the FD&C Act [21 U.S.C. § 360(j)] to reflect discontinuation of products (21 CFR 207.21(b)). Questions about electronic drug listing updates should be sent to **eDRLS@fda.hhs.gov (mailto:eDRLS@fda.hhs.gov)**. In addition to the required update, firms can also notify the Agency of product discontinuation by sending a letter, signed by the firm's chief executive officer and fully identifying the discontinued product(s), including the product NDC number(s), and stating that the manufacturing and/or distribution of the product(s) have been discontinued. FDA plans to rely on its existing records, including its drug listing records, the results of any future inspections, or other available information when considering enforcement action.

Your written notification should refer to the Warning Letter Number above (**CMS Case #490872**).

Please address your reply to John W. Diehl, Acting Director, Compliance Branch, at the FDA address provided. In addition, please submit a signed copy of your response to **john.w.diehl@fda.hhs.gov (mailto:john.w.diehl@fda.hhs.gov)**.

If you have questions regarding the contents of this letter, you may contact Mr. Diehl at (214) 253-5288.

Sincerely,
/S/
Monica R. Maxwell
Acting Program Division Director
Office of Pharmaceutical Quality Operations, Division II

CC:

Mary Mayleben
Pharmaceutical Program Manager
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