ROBERT MILLER & ASSOCIATES
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120 NEWPORT CENTER DRIVE www.expertlawfirm.com
NEWPORT BEACH, CA 92660

Wednesday, January 25, 2023

VIA EMAIL

In Re: *MAGI'S LAB SRL and sale of genetic and metabolic tests*

To Whom It May Concern:

Our law firm was asked to issue this correspondence as an opinion letter, regarding potential sale of products, specifically genetic and metabolomic tests.

The company at issue is an Italian Company, MAGI'S LAB SRL, which currently sells dietary supplements in the United States. They have established minimum contacts in the United States, including operating with FDA certification and obtaining an Employer Identification Number (EIN) for the corporation. The company also has a related spin-off company, called MAGISNAT, based at Atlanta Tech Park in Georgia.

MAGI'S LAB SRL intends to begin selling tests in a direct-to-consumer format, through Amazon's FBA program and in other markets. Specifically, the tests they intend to sell in U.S markets are a (1) DNA Wellness Test, which analyzes polymorphins (SNPs), which give an indication on how to improve nutrition, physical activity, and recovery; and (2) A metabolomics test to direct consumers as to nutritional advisements.

MAGI'S LAB SRL, at the time of this opinion, does hold an ISO 15189 laboratory certification, which allows it to sell tests belonging to the low-risk General Wellness Tests category, under Section 520(o)(4) of the FD&C Act. The company does not yet hold Clinical Laboratory Improvement Amendments (CLIA) certification but is moving towards that designation and certification.

The flowchart of Direct-To-Consumer Tests is as follows:

1. Online order from the customer.
2. Communication to the customer of the credentials to access his or her dedicated page.

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3. Completion of online forms including personal data and informed consent.
4. Shipping of biological material collection kit (saliva, through spit) non-IVD (In vitro diagnostic).
5. Shipment of the patient's biological material to the laboratory.
6. Acceptance of the biological sample.
7. Analysis of the biological sample.
8. Report communication to the client by uploading to his or her dedicated page.

As MAGI'S LAB SRL intends to sell the two tests above, belonging to the low-risk general wellness tests category, that are not medical devices, and as those are exempt from FDA regulations and can be sold without 510(k) clearance required for Class II medical devices, or pre-market approval required for Class III medical devices, and as both tests have no diagnostic or therapeutic purpose, there should not be a prohibition on these specific tests.

This opinion letter is only based upon the information provided and the status of The Act and cases based upon The Act and is subject to change as the law changes.

Please feel free to contact our office with any questions or concerns regarding this letter or this opinion letter in general.

Sincerely,

Signature: Robert L. Miller
Robert L. Miller (Jan 25, 2023 22:55 PST)

Email: magislabsrl@expertlawfirm.com

Robert L. Miller
Attorney at Law

ATTACHMENT 1- Email of request made by MAGI'S LAB SRL to FDA.

ATTACHMENT 2- EIN certificate.

Re:Support at FDA/DICE Re:Information Inquiry about Low Risk General Wellness Tests [ref:_00Dd0fegA._5003d66llr:ref]

Da **matteo.bertelli@assomagi.org** <matteo.bertelli@assomagi.org>
A **dice@fda.hhs.gov** <dice@fda.hhs.gov>
Ccn **kevin.donato** <kevin.donato@assomagi.org>, **Silvia Gaudenzi** <silvia.gaudenzi@assomagi.org>, **gabriele.bonetti** <gabriele.bonetti@assomagi.org>
Data martedì 6 dicembre 2022 - 12:11

Dear Industry Team,
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Thank you very much for your complete and comprehensive response, and for the advice to refer to an experienced medical device consultant for the "Genetich Health Risk Tests" category.

We would like to ask some last questions: are there any nutrition and wellness genetic tests that fall under the category of "General Wellness Products that Are Not Medical Devices"? If so, could you give us some examples? For example, we are considering investigating a series of genetic polymorphisms, conducted on saliva samples collected through spit in the collection kit (thus, without body contact), and aimed at promoting healthy lifestyles. Could they fall into this category? Are there any examples?

Thank you very much for your time. About the other matters, we are already looking for consultants.

Best regards,
MB

> Da ""DICE" <dice@fda.hhs.gov>" dice@fda.hhs.gov
> A "matteo.bertelli@assomagi.org" matteo.bertelli@assomagi.org
> Cc
> Data Mon, 5 Dec 2022 21:48:39 +0000 (GMT)
> Oggetto Support at FDA/DICE Re:Information Inquiry about Low Risk General Wellness Tests [ref:_00Dd0fegA._5003d66llr:ref]
>
> FDA U.S. FOOD & DRUG ADMINISTRATION
>
> Dear Matteo Bertelli:

Thank you for contacting the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH) DICE@fda.hhs.gov e-mail account.

Your company's genetic and metabolomic tests *might not* be general wellness products. Some of what you described, such as detecting nutritional deficiencies *could possibly* be considered diagnostic.

It is the device manufacturer's responsibility to determine if their product is a medical device. Section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act) defines a *medical device* as *an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)*. FDA regulations define IVDs as *reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease…These products are devices* [21 CFR 809.3(a)]. You may also want to read "Is my product a medical device?" on the "Medical Device Overview" page at https://www.fda.gov/industry/regulated-products/medical-device-overview. If your company is still unable to determine if your software app is a medical device, please send a description of the app, its intended use, its indications for use, how it operates, and other pertinent information to DeviceDetermination@fda.hhs.gov.

Examples of general wellness products include exercise equipment, audio recordings, video games, software programs, and similar products.

Your company should use the information above along with the general wellness guidance to determine whether your company's product is a general wellness product or an in vitro diagnostic (IVD) device. The general wellness guidance is:

General Wellness: Policy for Low Risk Devices Guidance for Industry and Food and Drug Administration Staff

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices

Here are the answers to the questions you asked in your email:

1. Is there a list of approved polymorphisms, claims, and methodology for low risk general wellness tests? Is it possible to have a review of our document made by a third party, which would be specialized in this matter and offering this service for a fee, to be sure that the product is compliant with the legislation?

There is no list of polymorphisms for low risk general wellness tests. Claims for low risk general wellness products are covered in the guidance, *General Wellness: Policy for Low Risk Devices Guidance for Industry and Food and Drug Administration Staff*.

You can hire an attorney who specializes in medical devices and/or a medical device consultant to help ensure that your company's test is compliant. It is a conflict of interest for the FDA to recommend anyone, but you can check with professional societies, search the web, etc. to find one.

2. Are the polymorphisms that are associated with the risk of anorexia, obesity, lymphedema and lipoedema in this category, or do they fall into the "genetic health risk test" category?

DICE provides educational resources regarding medical device laws, regulations, guidance documents, and policies, covering both premarket and postmarket topics. DICE provides general information about medical devices and directs stakeholders to educational resources. DICE staff are not subject matter experts, so we cannot answer that question. If you believe that your company's test requires a premarket application, your company should arrange a pre-submission (pre-sub) type of Q-sub interaction (Q-sub) [explained later in this email] with FDA subject matter experts to discuss those questions as well as how your company plans to validate the test if it requires a marketing application.

3. Which authorizations do we need to launch on the market tests of the "Low Risk General Wellness Test" category?

The general wellness guidance states, *CDRH does not intend to examine low risk general wellness products to determine whether they are devices3 within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations, including, but not limited to: registration and listing and premarket notification requirements (21 CFR Part 807); labeling requirements (21 CFR Part 801 and 21 CFR 809.10); good manufacturing practice requirements as set forth in the Quality System regulation (21*

CFR Part 820); and Medical Device Reporting (MDR) requirements (21 CFR Part 803).

Medical devices are classified as Class 1, 2 or 3. Class 1 devices have the least amount of risk and Class 3 devices have the most risk. An example of a Class 1 device is a manual toothbrush. An example of a Class 3 device is a battery-powered, implanted pacemaker. Device classification is heavily driven by the product's intended use and the risk posed by the device if it were to fail, so different device classifications have different regulatory requirements with regard to demonstrating safety and efficacy. Most Class 1 devices are exempt from the premarket submission requirement, but some do require 510(k)s. Moderate risk devices (mostly Class 2 devices) require 510(k) review. Such devices are tested and shown to be Substantially Equivalent (SE) to a device that is already cleared for marketing in the U.S. (predicate device). There are CDRH Learn presentations about 510(k)s in the "How to Study and Market Your Device" section of CDRH Learn. FDA approval is required for the highest risk devices. Class 3 devices are usually life-saving or life-sustaining devices, devices that are implanted for more than one year, devices of substantial importance in preventing impairment of human health, or devices which present a potential, unreasonable risk of illness or injury. Such devices require premarket approval (PMA, FDA approval).

All medical device manufacturers must comply with the General Controls. The General Controls include prohibitions against adulteration, misbranding and banned devices as well as requirements for records and reports. General Controls also include: Labeling in 21 CFR 801, Medical Device Reporting in 21 CFR 803, Medical Devices; Reports of Corrections and Removals in 21 CFR 806, Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices in 21 CFR 807 and the Quality System Regulation (QSR)/Good Manufacturing Practices (GMPs) in 21 CFR 820. A device that requires 510(k) clearance usually requires Special Controls. Special Controls may include performance standards, special controls documents, guidance, special labeling requirements, postmarket surveillance or other controls. Special Controls data such as results of testing to performance standards are included in the data in the 510(k) submission. Class 3 devices require PMAs.

If you believe that your company's test may require a premarket application, your company should arrange a pre-sub type of Q-sub with FDA subject matter experts to discuss those questions as well as how your company plans to validate the test if it requires a marketing application. Pre-sub questions must be relevant to a planned marketing application. Here is the link to the guidance document:

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: Guidance for Industry and Food and Drug Administration Staff

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

The pre-sub request cover letter should include the contact information for your company's point-of-contact (POC, also known as the official correspondent) and the type of Q-sub you are requesting (pre-sub). If your company is requesting the pre-sub as a teleconference, you should include a draft agenda, at least 3 preferred meeting dates and the planned attendees in the cover letter. The pre-sub request should include the purpose of the pre-sub, a description of the device including how it operates, the intended use or indications for use and the regulatory history of the device and/or similar devices. Detailed information about the content of the pre-sub cover letter and pre-sub request is on pages 11 – 13 of the Q-Submission guidance.

Your company's pre-sub requires the CDRH Premarket Review Submission Cover Sheet (Form FDA 3514) at https://www.fda.gov/media/72421/download.

Your company's pre-sub request also requires an eCopy There is information about eCopies at https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions. Here is a link to the eCopy guidance:

eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions

Please download the eCopy Validation Tool for your operating system (these are also linked on the eCopy web page):

- Download Windows 64-Bit Version
- Download Windows 32-Bit Version
- Download Mac Version

Please see the eCopy guidance linked above for examples and exhibits of an eCopy.

The most common errors that result in an eCopy hold are:

- PDF files that don't comply with the naming convention. For example, PDF files that do not begin with the file name (001_, 002_, 003_ etc.)

- Non-PDFs that were not zipped. These are Non-PDFs that were not zipped inside of the "MISC FILES" or "STATISTICAL DATA" folders.

- Non-PDFs that were not placed in the correct folder. These are Non-PDFs that were saved outside of the "MISC FILES" or " STATISTICAL DATA" folders.

- Volume names that contain unacceptable symbols. The list of acceptable symbols can be found in the eCopy guidance.

Other eCopy errors that can result in an eCopy hold include:

- Oversize PDF files: An individual PDF larger than 50MB will fail the loading process. Check the size of each PDF on your CD, DVD, or flash drive to determine if it exceeds 50MB. Note: There is currently no size limit for the overall eCopy.

- Missing company cover letters: For replacement eCopies, the FDA needs a paper copy of your company cover letter including a signature, so that they can process the replacement eCopy. The FDA date-stamps the company cover letter with the receipt date of your replacement eCopy. In other words, you need to resubmit a company cover letter with every replacement eCopy.

- Issues from previous submissions: Each eCopy is its own entity. It does not matter if you are providing an original submission or a response to a deficiency letter. You must start anew each time and create an eCopy that meets the technical standards of Attachment 1 in the eCopy guidance for the specific content that you want to submit. You do NOT build your eCopy as a cumulative product for which you continue PDF or volume numbering, or try to match 3-digit prefixes that you assigned for the previous submission. Instead, the PDF numbering starts back at 001_ and, if you have a volume-based submission, then the volume numbering starts back at VOL_001.

Your company may now send your eCopy pre-sub request online through the CDRH Customer Collaboration Portal ("CDRH Portal"). the CDRH Portal now allows anyone to register for a CDRH Portal account to send an eCopy online. You may create a CDRH Portal account at https://fda-cdrh.okta.com/signin/register. The CDRH Portal is voluntary for fiscal year (FY) 2023, but will become mandatory in FY 2024.

If you have general medical device regulatory questions, please email them to DICE@fda.hhs.gov. Additionally, please feel free to refer to DICE's educational resources Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH

Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). You can view information about the most recent Regulatory Education for Industry (REdI) conferences. Recordings of the 2022 REdI presentations are at https://www.fda.gov/drugs/news-events-human-drugs/regulatory-education-industry-redi-annual-conference-2022-06062022?utm_medium=email&utm_source=govdelivery. Recordings of the 2022 REdI presentations are on YouTube. Day 3 is at https://www.youtube.com/watch?v=9t74xtVNoDw and day 4 is at https://www.youtube.com/watch?v=_7gtsP468tY. Recordings of the 2021 REdI presentations are at https://sbiaevents.com/redi2021/#files.

Best regards,

Industry Team
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Original Message
From: matteo.bertelli@assomagi.org
Sent: 12/5/2022

Subject: Information Inquiry about Low Risk General Wellness Tests
Message:

Dear Sir/Madam,

We are a spin-off project, which is going to be turned into an actual

company at Atlanta Tech Park (https://magisnat.com/contact). We are currently selling food supplements in the US via Amazon US, but we are developing some genetic and metabolomic tests, which, as far as we know, fall into the “Direct to Consumer” category (https://www.fda.gov/medical-devices/in-vitro-diagnostics/direct-consumer-tests), sub-category “Low Risk General Wellness Test” (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices).

We have a few questions to ask you, given the following facts:
1. On our tests and reports, it would clearly be stated that they do not have diagnostic or therapeutic purposes;
2. Our laboratory analyzes some SNPs (genetic polymorphisms) that are related to nutritional deficiencies, weight loss, responses to exercise. We follow a classical approach, based on literature data, and also an approach that is based on polygenic risk score;
3. The test will be carried out in a laboratory outside the US, which does not have the CLIA and ISO 9001:17025 certifications;
4. We would like to carry out the sample collection using saliva as biologic material (via a non-invasive test).

The questions are the following:
1. Is there a list of approved polymorphisms, claims, and methodology for low risk general wellness tests? Is it possible to have a review of our document made by a third party, which would be specialized in this matter and offering this service for a fee, to be sure that the product is compliant with the legislation?
2. Are the polymorphisms that are associated with the risk of anorexia, obesity, lymphedema and lipoedema in this category, or do they fall into the “genetic health risk test” category?
3. Which authorizations do we need to launch on the market tests of the “Low Risk General Wellness Test” category?

Looking forward to hearing from you soon.

Best regards,

Matteo Bertelli

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X

IRS DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

Date of this notice: 07-19-2022

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Employer Identification Number:
32-0694438

Form: SS-4

Number of this notice: CP 575 E

MAGIS LAB SRL
18 BRIDGE STREET 2A
BROOKLYN NY 11201

For assistance you may call us at:
1-800-829-4933

002553

IF YOU WRITE, ATTACH THE
STUB OF THIS NOTICE.

WE ASSIGNED YOU AN EMPLOYER IDENTIFICATION NUMBER

Thank you for applying for an Employer Identification Number (EIN). We assigned you EIN 32-0694438. This EIN will identify your entity, accounts, tax returns, and documents, even if you have no employees. Please keep this notice in your permanent records.

Taxpayers request an EIN for their business. Some taxpayers receive CP575 notices when another person has stolen their identity and are opening a business using their information. If you did not apply for this EIN, please visit, www.irs.gov/einnotrequested.

When filing tax documents, making payments, or replying to any related correspondence, it is very important that you use your EIN and complete name and address exactly as shown above. Any variation may cause a delay in processing, result in incorrect information in your account, or even cause you to be assigned more than one EIN. If the information is not correct as shown above, please make the correction using the attached tear-off stub and return it to us.

When you submitted your application for an EIN, you checked the box indicating you are a non-profit organization. Assigning an EIN does not grant tax-exempt status to non-profit organizations. Publication 557, Tax-Exempt Status for Your Organization, has details on the application process, as well as information on returns you may need to file. To apply for recognition of tax-exempt status, organizations must complete an application on one of the following forms: Form 1023, Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code; Form 1023-EZ, Streamlined Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code; Form 1024, Application for Recognition Under Section 501(a); or Form 1024-A, Application for Recognition of Exemption Under 501(c)(4) of the Internal Revenue Code.

Nearly all organizations claiming tax-exempt status must file a Form 990-series annual information return (Form 990, 990-EZ, or 990-PF) or notice (Form 990-N) beginning with the year they legally form, even if they have not yet applied for or received recognition of tax-exempt status.

Unless a filing exception applies to you (search www.irs.gov for Annual Exempt Organization Return: Who Must File). We start calculating this three-year period from the tax year we assigned the EIN to you. If that first tax year isn't a full twelve months, you're still responsible for submitting a return for that year. If you didn't legally form in the same tax year which you obtained your EIN, contact us at the phone number or address listed at the top of this letter.

For the most current information on your filing requirements and other important information, visit www.irs.gov/charities.

IMPORTANT REMINDERS:

* Keep a copy of this notice in your permanent records. This notice is issued only one time and IRS will not be able to generate a duplicate copy for you. You may give a copy of this document to anyone asking for proof of your EIN.

* Use this EIN and your name exactly as they appear at the top of this notice on all your federal tax forms.

* Refer to this EIN on your tax-related correspondence and documents.

* Provide future officers of your organization with a copy of this notice.

Your name control associated with this EIN is MAGI. You will need to provide this information, along with your EIN, if you file your returns electronically.

Safeguard your EIN by referring to Publication 4557, Safeguarding Taxpayer Data: A Guide for Your Business.

You can get any of the forms or publications mentioned in this letter by visiting our website at www.irs.gov/forms-pubs or by calling 800-TAX-FORM (800-829-3676).

If you have questions about your EIN, you can contact us at the phone number or address listed at the top of this notice. If you write, please tear off the stub at the bottom of this notice and include it with your letter. If you do not need to write us, do not complete, and return this stub.

Thank you for your cooperation.

(IRS USE ONLY) 575E 07-19-2022 MAGI 0 0235395736 SS-4

002553

Keep this part for your records. CP 575 (Rev. 1-2022)

Return this part with any correspondence so we may identify your account. Please correct any errors in your name or address.

CP 575 E

0235395736

Your Telephone Number
( ) -
_____

Best Time to Call
_____

DATE OF THIS NOTICE: 07-19-2022
EMPLOYER IDENTIFICATION NUMBER: 32-0694438
FORM: SS-4 NOBOD

INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

MAGIS LAB SRL
18 BRIDGE STREET 2A
BROOKLYN NY 11201