FDA inspection

In connection with the export of our products for the U.S. market, we were subjected to FDA

(Food Drug and Administration) inspections. The inspection took place in October 2019.

FDA inspectors checked whether our products intended for the US market are manufactured in accordance with strict US requirements. The American approach to dietary supplements is similar to that used in Europe for medicines. There are CFR requirements for supplements (equivalent to GMP), there is a pharmacopoeia for supplements. This already indicates that the inspection was at a level similar to the Pharmaceutical Inspection. The inspection was conducted in accordance with the requirements of CFR 21.I.B.111

Below is the title of the guide and the link to it

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION

PART 111 [CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=111&showFR=1)

The following areas were inspected, giving the main ones:

* personnel,
* machinery and equipment
* documentation
* manufacturing
* quality control
* storage and distribution
* outsourced activities
* complaints, quality defects and product recalls
* internal Inspections

The Agency's officials checked the conditions under which our products are manufactured, and thus confirmed that they meet the requirements they set for exporters.

The FDA not only controls food, including dietary supplements, medicines, medical devices but also cosmetics and veterinary products. Its ruling is an indicator of product quality and safety. The inspection ended in a positive result.

The FDA does not issue certificates, and a confirmation is our placement in the FDA database.

Attached is proof that the result of the inspection was positive (in the Classification section you can see NAI, which means No Action Indicated)

Below is a link to search results in the FDA database

<https://www.accessdata.fda.gov/scripts/inspsearch/results.cfm?start=1&end=100&textSearch=Olimp%20Laboratories&classification=&state=&project=&inspDateEndFrom=&inspDateEndTo=&classificationDecision=&country=&city=&zip=&center=&sortBy=&district=>

The FDA has found that both production sites (Nagawczyna, Pustynia) meet the GMP requirements for dietary supplements established by the US.

Below is also a link to the CFR document with which Olimp had to comply in order for the FDA to declare our company compliant with US GMP standards for dietary supplements.

<https://www.ecfr.gov/cgi-bin/text-idx?SID=edd75688ebd26aa4d4a4cede546be22a&mc=true&node=pt21.2.111&rgn=div5>

In the report, the inspector stated that he did not find any adverse conditions that would justify issuing FDA 483 Inspectional Observations. Therefore, the FDA 483 Inspectional Observations document has not been issued for Olimp, which amounts to a lack of non-compliance.