

AHPA REPORT

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Special Topics

FDA records show dietary supplement recalls are relatively infrequent

2 percent of more than 800 recalls initiated in 2019 involved dietary supplements

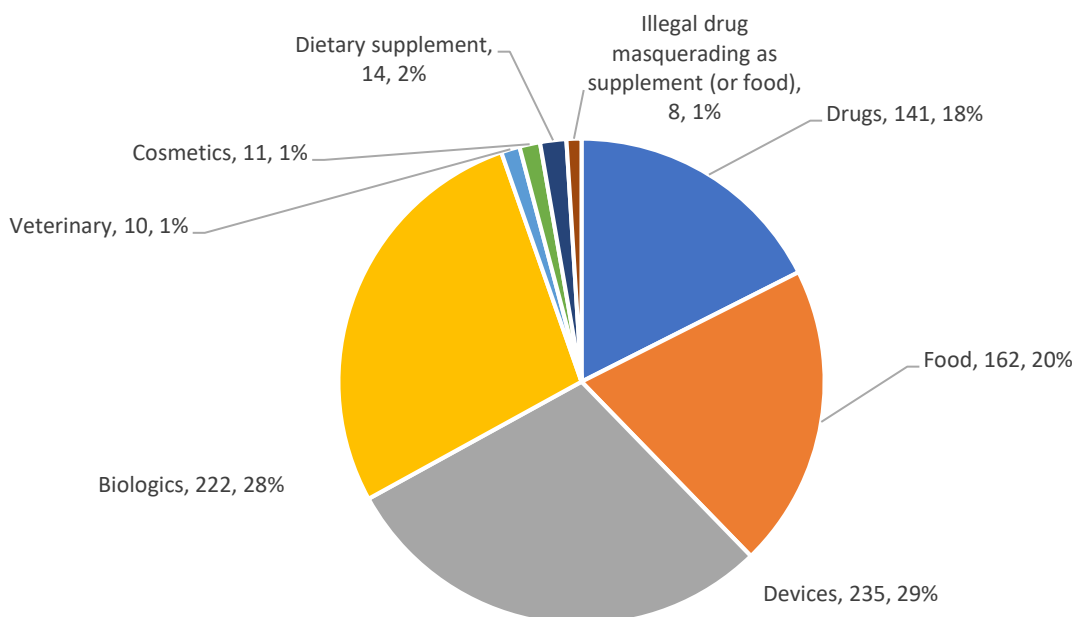
In analyzing recall data from the Food and Drug Administration (FDA), AHPA staff found that 14 of 803 (1.7 percent) recorded recalls initiated in 2019 involved dietary supplements, and among these, three were Class I recalls (the most serious recall class).

FDA is responsible for the safety of most foods (with some exceptions for meat, poultry, and certain egg products) including dietary

supplements, drugs (both prescription and non-prescription OTC drugs), biologics, medical devices, radiation-emitting products, cosmetics, veterinary products, and tobacco products (See <https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate>, accessed 6/27/2019). These regulatory activities include tracking and reporting on product recalls.

FDA enforcement reports documenting these recalls are regularly distributed by the agency and are available for public review through the agency's internet Recall Enterprise System (iRES) (available at <https://www.accessdata.fda.gov/scripts/ires/index.cfm>, accessed 6/27/2019). AHPA's analysis is based on iRES data released by the agency through June 26, 2019, which recorded 803 recall events initiated in calendar year 2019 (see **Methods**, below, for more details). Note that there are some limitations as to what conclusions can be drawn from this data (see

Recalls by product category (iRES 1/1/2019-6/26/2019)



AHPA REPORT

Limitations, below) as recalls included in this data include those which FDA had assigned to one of three health hazard classes and not necessarily all safety recalls conducted during the period reviewed. The number of products in the market in each class also varies, which may affect recall rates.

Of the 803 recalls recorded in iRES in this period, 29 percent were recorded for medical devices and 28 percent for biological products. Drug products accounted for 18 percent of these recalls and 20 percent were for conventional foods. AHPA identified 1.7% of recalls involved dietary supplement products.

Recalls could include multiple products; while 73% of the categorized recalls included a single product, 11% included 2 products, and the remaining 16% 3 or more products. The recall with the most distinct products was a Class II recall involving a series of

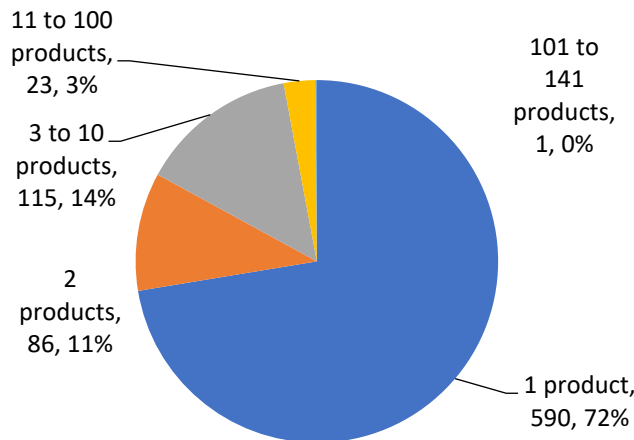
141 related cardiovascular devices.

FDA assigns voluntary recalls a classification based on a health hazard evaluation:

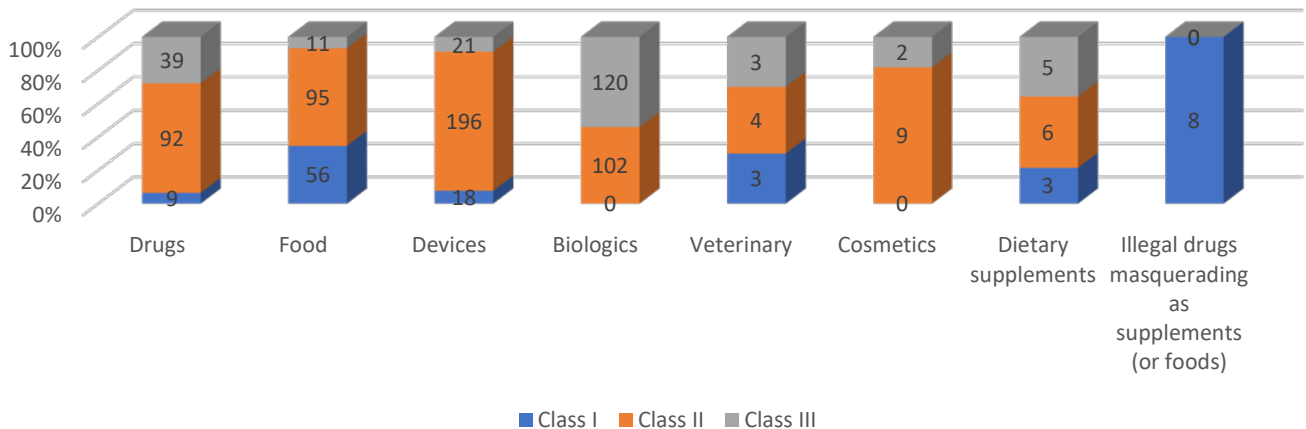
- **Class I** -- A reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death
- **Class II** -- Use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote

- **Class III** -- Use of, or exposure to, a violative product is not likely to cause adverse health consequences
- Eleven of the 14 dietary supplement recalls (nearly 79 percent) from the reviewed period in 2019 were classified as Class II or Class III, and three (21 percent) were identified as Class I.

Number of products per recall (iRES 1/1/2019-6/26/2019)



Recall class by product type, percentage (iRES 1/1/2019-6/26/2019)

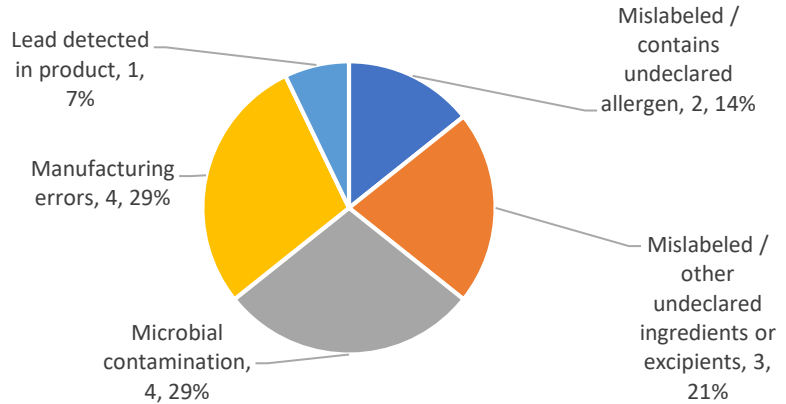


AHPA REPORT

This is similar to recalls for devices and drugs, to which FDA assigned a Class III designation more frequently than Class I designations. In this same time span, conventional foods were recalled with a Class I designation slightly more frequently than Class III, with 56 recorded Class I recalls (32 percent of all food recalls) between January and June 26, 2019. Recalls of biologics and cosmetics categorized during this time period landed exclusively in Class II and Class III.

Among the dietary supplement recalls conducted in 2019 and classified by FDA between January 1, 2019, and June 26, 2019, the most common reasons for conducting a recall were the risk of microbial contamination (29%, 4 cases) or mislabeling, including incorrect amounts of ingredients and omitted

Number of supplement recalls and reason for recall (iRES 1/1/2019-6/26/2019)



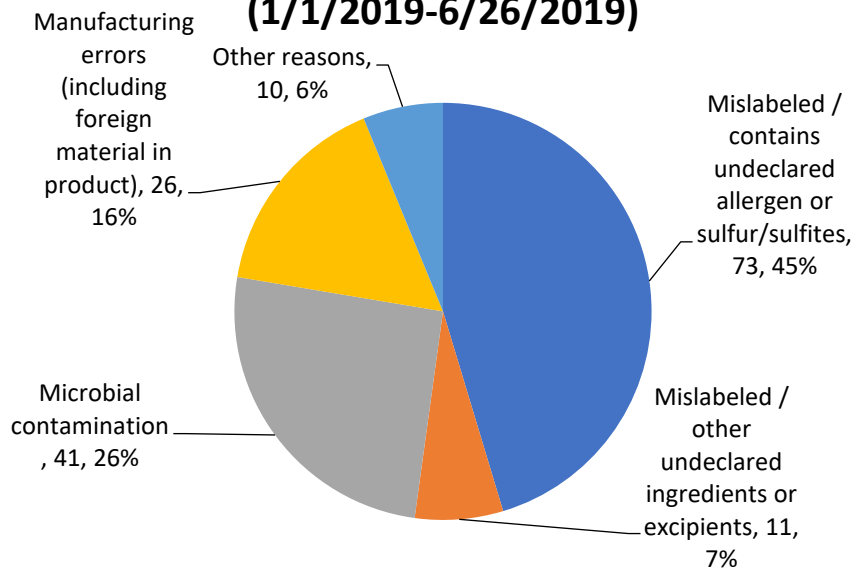
excipients (21%, 3 cases), or the presence of unlabeled allergens, (14%, 2 cases).

During this same period, 162 recalls were conducted involving non-dietary supplement food products. Of these recalls, 45% (73 cases) regarded undeclared allergens or the presence of sulfur or sulfites and 26% (41 cases) were related to microbial contamination,

manufacturing errors (usually involving foreign material in the product) were seen 16% of the time (26 times), and 7% (11 recalls) were based on mislabeling.

“These recall data provide additional evidence of the overall safety of the dietary supplement class,” said AHPA Chief Information Analyst Merle Zimmermann, Ph.D. “AHPA also regularly reviews other dietary supplement safety resources, including mandatory serious adverse event reports and recorded observations from FDA inspections, and

Number of food product recalls and reason for recall (1/1/2019-6/26/2019)



AHPA REPORT

the results suggest that current supplement laws and regulations are working effectively to protect consumer safety and ensure a marketplace of high-quality, safe products.”

Among the 803 recalls analyzed, there were seven cases where FDA indicated that the recalled products were illegal drugs masquerading as dietary supplements and one where the illegal drug was labeled as a conventional food. All of these recalls were classified by FDA as Class I recalls, and have been separated from the other categories above. These illegal products are archived on AHPA’s Keep Supplements Clean website (<http://www.keepsupplementsclean.org/>), a free resource to inform consumers, the dietary supplement industry, and other stakeholders of issues related to illegal, tainted products with false labels. In each of these cases, products were labeled as either conventional foods or dietary supplements, but when tested they were found to contain undeclared illegal drug ingredients. The regulated supplement industry continues to vocally support FDA’s using its existing authority to fully enforce current laws and regulations to remove these illegal products from the market.

Methods

This article discusses 803 product recalls that FDA reported through iRES as initiated in 2019 and which the agency classified into recall classes between January 1 and June 26, 2019. AHPA staff obtained the reported data by conducting searches in the iRES system for recalls classified each month in 2019. While the goods involved are categorized by class as either biologics, cosmetics, devices, drugs, food, tobacco, or veterinary products, FDA does not separately categorize recalls for dietary supplements (a subcategory of food), so reported recall data for dietary supplement products were identified based on a review of information on recalls within the “food” and “drug” product categories from this period. Recalls involving known drugs, products

marketed as drugs, and conventional foods were removed, and the remainder individually checked to validate if labels identified the recalled products as dietary supplement products.

Limitations

The present analysis covered just the approximately six-month period from January 1 to June 26, 2019. AHPA has not previously conducted such analysis so does not assert that the data from this particular time period represents the normal pattern of recalls for FDA-regulated consumer goods. Also, the fact that the raw number of recalls may be higher for any particular category does not necessarily mean that a recall is more likely for that category since this analysis has not accounted for the total number of products marketed in the category, or any other factor that may influence any such perception. In addition, virtually all recalls are voluntary and many are initiated by a firm after identifying a potential problem that is not a certain health risk. It should also be understood that the numbers provided here may not indicate the total number of recallable products or events in any of the identified categories since some firms may not issue a recall when faced with the same criteria that lead another to do so.

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