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Washington, DC 20548

October 18, 2018

The Honorable Claire McCaskill  
Ranking Member  
Committee on Homeland Security and Governmental Affairs  
United States Senate

The Honorable Robert P. Casey, Jr.  
Ranking Member  
Special Committee on Aging  
United States Senate

### Memory Supplements: Results of Testing for Selected Supplements

The number of dietary supplements<sup>1</sup> on the market has grown exponentially from an estimated 4,000 products in 1994 to an estimated 80,000 products in 2016, according to officials in the U.S. Department of Health and Human Services' (HHS) Food and Drug Administration (FDA). As the number of dietary supplements on the market has increased, specialty supplements that claim to address specific health issues, including those claiming to address memory or memory loss (referred to in this report as memory supplements), have emerged in the market.<sup>2</sup> Available data indicate that memory supplements constitute a small segment of the overall dietary supplement market, but their sales nearly doubled in value from 2006 to 2015, increasing from \$353 million to \$643 million.<sup>3</sup> Consumers searching to prevent or treat age-related memory loss, including Alzheimer's disease, have increasingly turned to dietary supplements for help.<sup>4</sup>

The regulation of memory supplements falls under FDA's general authority to regulate dietary supplements and labeling of dietary supplements, and the Federal Trade Commission's (FTC) authorities related to advertising. These authorities generally do not apply until after

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<sup>1</sup>The Dietary Supplement Health and Education Act of 1994 (DSHEA) defines a dietary supplement as a product (other than tobacco) that, among other requirements, is intended to supplement the diet; contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their constituents; is intended to be taken by mouth in certain forms, such as a pill, capsule, tablet, or liquid; and is labeled as a dietary supplement. DSHEA places dietary supplements in a special category under the umbrella of foods.

<sup>2</sup>For the purposes of this report, we use the term *memory supplement* to refer to a dietary supplement that claims to improve or in other ways positively affect memory, as exhibited by the claims on its label or advertising. Claims may involve proxies for memory loss such as cognitive function, brain power, and absentmindedness. Memory supplements may also be advertised or used for other purposes besides memory or cognitive function.

<sup>3</sup>Data for 2017 and 2018 are not yet available for the memory supplements market. The 2015 data were the most recent data available when GAO obtained them in 2017, and given the incremental growth projections for 2016, GAO considers the data as a reasonable reflection of the current size of the market for memory supplements.

<sup>4</sup>Dietary supplements generally are not permitted to claim to cure, treat, or mitigate diseases. If the label or labeling of a product marketed as a dietary supplement bears a disease claim (such as a claim to treat Alzheimer's disease) as defined in 21 C.F.R. § 101.93(g), the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies.

supplements go to market (postmarket). In 2009, we reported that weaknesses in the regulatory system for dietary supplements may increase the likelihood of unsafe products reaching the market.<sup>5</sup> Most recently, in a review of memory supplement marketing, we found that most product marketing (96 percent) occurred on the Internet. Also, while Internet marketing of supplements was a concern for FDA, FTC, consumers, and industry groups, we found that consumer groups were unclear about FDA's and FTC's roles overseeing Internet marketing of supplements, as the two agencies share oversight of marketing on the Internet.<sup>6</sup> As a result, we recommended that FDA and FTC provide further guidance related to their oversight of dietary supplement Internet marketing. In July 2017, FTC and FDA collaborated to issue a joint web post on FTC's consumer blog with information on each agency's differing roles in dietary supplement oversight, and encouraging consumers to report any concerns regarding the marketing or safety of supplements. In addition to limitations in oversight related to marketing, we found that FDA faced oversight challenges related to limited information about the dietary supplement market, including memory supplements, such as lack of current and accurate data on ingredients and products on the market that could inform oversight. We noted that according to FDA officials, the agency was exploring ways to obtain better market information to inform oversight efforts.

Given questions about the effect on senior citizens of the growing memory supplement market, you asked us to have selected memory supplements tested. This report examines the extent to which selected memory supplements contained: (1) their stated ingredients at the quantities stated on their labels and specific adulterants, and (2) certain contaminants.<sup>7</sup>

We contracted with a qualified and vetted testing laboratory to conduct testing on three memory supplement products. These products are a nongeneralizable sample selected from a list of highly advertised memory supplements identified through our May 2017 report.<sup>8</sup> We selected the three products from the top 10 most-advertised products identified in our previous report, and based on the popularity of their main ingredient, number of ingredients, and availability of the product from major retailers.<sup>9</sup> We purchased supplements for testing online and in stores, through major retailers or directly from the supplement companies. The tested products were marketed as a *Ginkgo biloba* supplement,<sup>10</sup> a specialty memory supplement (which contained multiple ingredients including *Ginkgo biloba*), and a fish oil supplement. Different supplement companies produced all the selected products, and we masked the product names and brands

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<sup>5</sup>GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, [GAO-09-250](#) (Washington, D.C.: Jan. 29, 2009).

<sup>6</sup>GAO, *Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness*, [GAO-17-416](#) (Washington, D.C.: May 16, 2017).

<sup>7</sup>Under the Federal Food, Drug, and Cosmetic Act, food, including a dietary supplement, generally is adulterated if it contains any poisonous or deleterious substance which may render it injurious to health, or if any valuable constituent has been in whole or in part omitted, among other reasons. 21 U.S.C. § 342(a)(1) and (b)(1).

<sup>8</sup>We assessed the marketing frequency of different memory supplement products in our prior report, [GAO-17-416](#).

<sup>9</sup>We determined the popularity of a supplement's main ingredient based on market data we collected for our prior report, [GAO-17-416](#).

<sup>10</sup>*Ginkgo biloba* is one of the world's oldest living tree species and has been used for many years for a variety of medicinal purposes. *Ginkgo biloba* extract, made from the leaves of the *Ginkgo biloba* tree, is marketed to consumers as a herbal supplement. People take *Ginkgo biloba* for a wide variety of reasons, mostly to improve brain function and memory.

on the samples provided to the laboratory. The laboratory scientists tested two samples each of the *Ginkgo biloba* supplement and the specialty memory supplement. They tested three samples of the fish oil supplement. Testing for all seven samples included: ingredient identity<sup>11</sup> and quantity testing for selected ingredients listed on the label<sup>12</sup> and testing for certain dangerous contaminants (arsenic, cadmium, chromium, lead, and mercury) in the samples. Fish oil samples were also tested for additional contaminants, including polychlorinated biphenyls (PCB) and dioxins. The contaminants we selected for testing were identified as common contaminants based on our review of literature related to contaminants in the selected supplement types. Laboratory scientists also tested for adulterants in selected supplements containing *Ginkgo biloba*.

The results of this testing are limited to the highly advertised supplement samples we had tested and are not projectable to the entire universe of memory supplements. While we tested for certain contaminants, it is unknown whether other contaminants may be present in the selected supplements. However, we determined that these tests were suitable for our intended purposes. We did not test the efficacy of the selected supplements.

Technical experts from GAO interviewed scientists from the testing laboratory and reviewed all data and results related to the testing of the memory supplement samples discussed in this report. Specifically, we reviewed the laboratory's instrumental methods; testing protocols; quantitative and qualitative results, including chromatograms; and validation data.<sup>13</sup> We also examined peer-reviewed literature describing protocols for supplement testing. We determined that the laboratory data were sufficiently reliable for our purposes.

We conducted this performance audit from May 2017 to October 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, we found that two of the three memory supplement products tested either did not contain their stated ingredients or did not contain the ingredient quantity stated on the label. The *Ginkgo biloba* single-ingredient product we had tested was determined by laboratory scientists to contain no *Ginkgo biloba*, and was found to be adulterated with one or more substitute ingredients.<sup>14</sup> A second memory supplement product we had tested, which contained multiple ingredients, contained lower amounts of ingredients than claimed on the label for at least two of the three ingredients tested. In addition, the laboratory found that the *Ginkgo biloba* in that

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<sup>11</sup>Ingredient identity testing included verifying the presence of a stated dietary ingredient.

<sup>12</sup>For fish oil and *Ginkgo biloba* products, we had the laboratory test for all dietary ingredients. For the multi-ingredient memory supplement, we selected three of the seven dietary ingredients listed on the label for testing based on ingredient amount and commonality of ingredient. Given the costs of implementing tests for all seven dietary ingredients, we instead prioritized multiple samples for a subset of ingredients to bolster the reliability of our results.

<sup>13</sup>A chromatogram is the output from chromatography, a set of chemical analysis techniques for separating the components of a mixture.

<sup>14</sup>The laboratory determined that the product was adulterated, based on the results of its tests. We reviewed the laboratory's methods and data and verified that the test results were reliable. However, here and throughout the report, we do not make a determination that the laboratory results met the legal definition of "adulterated" under 21 U.S.C. § 342 and FDA regulations. That determination can only be made by FDA.

memory supplement product was adulterated with substitute ingredients. We will refer these products and the results of our testing to FDA for review and possible investigation, in coordination with FTC as appropriate. The fish oil product, the third memory supplement product we had tested, contained stated ingredients at quantities above the label amounts. Lastly, the laboratory found trace amounts of contaminants in the selected supplement products, but at levels considered safe.

## **Background**

There is no federal law defining the subset of dietary supplements we refer to in this report as memory supplements. There is also no definitive source of data regarding dietary supplements, including memory supplements, on the market, since federal law does not require that dietary supplements be listed with FDA or another federal agency. Dietary supplement data from the National Institutes of Health estimate the number of memory supplement products at almost 500 in 2016, but agency officials believe this is likely a low estimate. In 2015 memory supplement sales accounted for nearly 2 percent of total dietary supplement sales in that year, which totaled about \$39 billion. Fish oils were the most popular memory supplement in 2015, with sales of \$250 million, while *Ginkgo biloba* products were the third-most popular type of memory supplement, with \$78 million in sales in that year.

### Oversight of Memory Supplements

FDA and FTC share responsibility for oversight of dietary supplements and related marketing, with FDA generally responsible for safety, quality, and labeling, and FTC generally responsible for advertising. FDA and FTC authorities related to dietary supplements are generally limited to after dietary supplements go to market. FDA does not have the authority to require dietary supplements to be approved for safety or effectiveness before they are sold to consumers, as it does for drugs. However, dietary supplement firms must meet federal requirements for such supplements related to quality and labeling elements, including the following.

**FDA Quality Requirements.** FDA established current good manufacturing practice (CGMP) regulations for dietary substances describing the conditions under which supplements must be manufactured, packed, labeled, and held. These requirements apply to persons and firms that manufacture, package, label, or hold dietary supplements.<sup>15</sup> They were implemented in phases, according to company size, and became fully effective in 2010. CGMPs establish the minimum standards for activities related to manufacturing, packaging, labeling, or holding dietary supplements for the purposes of ensuring the product's quality throughout the manufacturing process to minimize the risks of a potentially unsafe or otherwise illegal product from reaching the marketplace. Following CGMPs should ensure that final products do not include the wrong ingredients; too much or too little of a dietary ingredient; contaminants such as natural toxins, bacteria, pesticides, glass, lead, or other heavy metals; or improper packaging or labeling.

CGMPs require that dietary supplement firms confirm the identity of supplement ingredients used to create the product, and also require firms to test or examine a sample of a finished product to determine that it meets product specifications. These specifications would include ingredient identity and product composition, and limits on contaminants.

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<sup>15</sup>If a firm stores dietary supplement products in a warehouse for distribution to another location, that firm holds dietary supplements and is subject to CGMP.

FDA inspects firms that manufacture, pack, or hold dietary supplements for compliance with current CGMP regulations, among other things. According to FDA officials, an inspection may include product examinations, sampling, and testing, as well as inspection of the firm and facility involved with dietary supplements. According to FDA officials, and consistent with the FDA Food Safety Modernization Act, FDA uses a risk-based approach to inspect firms that manufacture foods, including dietary supplements. The agency inspects firms it deems as high risk once every 3 years and other firms once every 5 years.<sup>16</sup>

**FDA Required Labeling Elements.** FDA regulations implementing DSHEA require that dietary supplement labels include, among other things, a statement of identity that identifies the product as a supplement, a list of dietary ingredients contained in the product, and the quantity of such ingredients in the product.

**FTC Oversight of Advertising.** FTC has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods (including dietary supplements), among other things, and exercises primary jurisdiction over all matters regulating the truth or falsity of advertising of foods.

### Adulterated and Misbranded Supplements

The Federal Food, Drug and Cosmetic Act defines adulteration to include, among other things, food wherein any valuable constituent has been in whole or in part omitted, any substance has been substituted wholly or in part, any damage or inferiority has been concealed, or any substance has been added to increase bulk or weight or reduce its quality or strength.<sup>17</sup> A dietary supplement is considered misbranded if, among other things, its labeling is false or misleading or presents health-related claims that are inconsistent with FDA regulations.<sup>18</sup> Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. These firms are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all legal requirements. FDA has the authority to take action against adulterated and misbranded dietary supplements. If FDA determines that there is a reasonable probability that a supplement is adulterated in any way, or misbranded for reasons relating to allergen labeling, and the use of or exposure to the product will cause serious adverse health consequences, and the dietary supplement firm declines to conduct a voluntary recall, FDA may order the firm to recall the product.<sup>19</sup>

### Supplement Contaminants

Heavy-metal contaminants including arsenic, cadmium, chromium, lead, and mercury can result in severe health consequences if consumed at high levels. For example, exposure to many of these contaminants has been linked to increased risk of cancer. While these contaminants can be toxic at high levels, eliminating them entirely from the food supply is not always possible because these metals are found in the air, water, and soil, and subsequently may enter the food

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<sup>16</sup>Pub. L. No. 111-353, § 201(a), 124 Stat. 3885, 3923 (2011) (adding 21 U.S.C. § 350j(a)).

<sup>17</sup>21 U.S.C. § 342(b).

<sup>18</sup>21 U.S.C. § 343.

<sup>19</sup>21 U.S.C. § 350l.

supply. Similarly, PCBs are a contaminant that may be found in certain high-fat foods, such as fish. PCBs are manufactured chemicals that were used for a number of industrial purposes, until they were banned in 1979 based on their potential to increase risk of cancer. FDA and the Environmental Protection Agency (EPA) have set limits on the amounts of certain harmful contaminants that may be present in water or food.

**Selected Supplements Did Not Contain Stated Ingredients or Ingredient Quantity for Two of Three Products Tested**

*Ginkgo Biloba* Single-Ingredient Product Did Not Contain *Ginkgo Biloba*, and Instead Contained Substitute Ingredients

The supplement labeled as a *Ginkgo biloba* supplement that we had tested did not contain *Ginkgo biloba*, and the laboratory determined it was intentionally adulterated with one or more substitute ingredients. We instructed the laboratory to test two samples of the supplement, and both samples had the same results. Laboratory scientists could not determine the exact source of the adulterants; as such, the safety of the substituted product is unknown. According to the supplement’s label, the product should contain 120 milligrams (mg) of *Ginkgo biloba* in each serving of the supplement, but the laboratory did not identify *Ginkgo biloba* in the product (see table 1). The product was advertised as containing “ultra pure” ingredients that would enhance memory and brain function. The label also claimed that the product was verified using high-performance liquid chromatography, which is a testing method that was also used by the laboratory to determine that the product was adulterated. On the basis of these results, we will refer this product and the results of our testing to FDA for review and possible investigation, in coordination with FTC as appropriate.

**Table 1: *Ginkgo Biloba* Single-Ingredient Product Testing Results**

Ingredient tested	Ingredient identified in product?	Amount of ingredient	Amount of ingredient advertised on label (milligrams per serving)
<i>Ginkgo biloba</i> extract (leaf)	No	None detected	120

Source: GAO analysis of testing data. | GAO-19-23R

The adulteration of *Ginkgo biloba* products is a common supplement industry occurrence, according to the laboratory scientists who tested the supplements and published research. According to the laboratory scientists, *Ginkgo biloba* is an expensive ingredient and there is an economic incentive to use cheaper substitute ingredients, referred to as economic adulteration. Literature we reviewed shows that this type of adulteration of *Ginkgo biloba* products is a known issue. However, it may be difficult to mitigate or detect because of the complicated supply chain and lack of expertise in methods that effectively detect the adulteration. For example, the laboratory scientists stated that the supply chains for supplements can be complex, with ingredients sold and resold by multiple suppliers before making it to the final product, and it can be difficult to track the source of an adulterated ingredient. In addition, while CGMP requirements state that dietary supplement firms should conduct identity and purity testing of ingredients, in practice testing is sometimes conducted in such a way that it would not catch the adulteration, and therefore does not satisfy these requirements. According to the laboratory scientists, supplement firms may lack the expertise to conduct thorough testing that would identify ingredient issues such as adulteration.

## Multi-Ingredient Memory Supplement Product Contained Lower Amounts of Ingredients Than on Label and Contained Substitute Ingredients

The supplement labeled as a multi-ingredient memory supplement product contained lower amounts of ingredients than claimed for at least two of three ingredients tested, and the laboratory found evidence of *Ginkgo biloba* adulteration (see table 2). We asked laboratory scientists to test the memory supplement product—a complex product with numerous ingredients—for three ingredients listed on the label, *Ginkgo biloba*, phosphatidylserine,<sup>20</sup> and ashwagandha.<sup>21</sup> The product is advertised to support and improve memory and concentration through its “clinically proven” ingredients. We will refer this product and the results of our testing to FDA for review and possible investigation, in coordination with FTC as appropriate.

**Table 2: Multi-Ingredient Memory Supplement Product Testing Results**

Ingredient tested	Ingredient identified in product?	Amount of ingredient (milligrams)	Amount of ingredient advertised on label (milligrams per serving)
<i>Ginkgo biloba</i> extract	Yes	Significantly less than label amount <sup>a</sup>	60
Phosphatidylserine	Yes	Less than label amount (88–93)	100
Ashwagandha extract	Yes	Could not be determined <sup>b</sup>	80

Source: GAO analysis of testing data. | GAO-19-23R

<sup>a</sup>While the laboratory did not report a precise quantitative amount for total *Ginkgo biloba* extract, testing found that the product contained about one-half of the amount of *Ginkgo* flavanol glycosides (a constituent of *Ginkgo biloba* extract) stated on the label.

<sup>b</sup>The laboratory could not comment on the quality of the ashwagandha extract due to interference from other components in the product.

Laboratory scientists confirmed the presence of *Ginkgo biloba*, but significantly less than the expected amount. Specifically, while the laboratory did not report a precise quantitative amount for total *Ginkgo biloba* extract, testing found that the product contained about one-half of the amount of *Ginkgo* flavanol glycosides (a constituent of *Ginkgo biloba* extract) stated on the label. Furthermore, laboratory scientists identified evidence of adulteration in the supplement samples tested, and stated that the evidence was also consistent with economic adulteration. As with the single-ingredient *Ginkgo biloba* we had tested, laboratory scientists found the presence of similar, but different materials that were used as a substitute for *Ginkgo biloba*.<sup>22</sup> Again, they could not determine the exact source of the adulterant or adulterants; as such, the safety of the substituted product is unknown.

Phosphatidylserine was present but in a lower amount than labeled. The laboratory found that there was between 7 and 12 percent less of the ingredient compared to the amount stated on the label. Lastly, laboratory scientists detected ashwagandha in the sample, but could not quantify the amount due to the complexity of the product and the presence of numerous

<sup>20</sup>Phosphatidylserine is a chemical that is present in brain cells and has been reported as important to normal brain cell functioning. Foods that may contain phosphatidylserine include fish, green leafy vegetables, soybeans, and rice.

<sup>21</sup>Ashwagandha is a common herb used in Ayurveda, the traditional system of medicine in India, and may also be referred to as “Indian Winter Cherry” or “Indian Ginseng.”

<sup>22</sup>The products we tested containing *Ginkgo biloba* are produced by different companies, and we are unaware of any relationship between these companies.

botanical ingredients. Laboratory scientists reported that they would require further information on the product ingredients and manufacturing process to determine the actual amount of ashwagandha. Because we did not have access to this information, they could not determine whether ashwagandha was present in the product at the amounts stated on the label.

**Fish Oil Product Contained Stated Ingredients and at Higher Quantities Than the Label Stated**

The supplement labeled as a fish oil product that we had tested contained omega-3 fatty acids (a component of fish oil) as claimed on the label, although at levels 8 to 13 percent higher than the amounts stated on the label (see table 3). Laboratory scientists stated that, in some cases, a supplement company may add greater amounts of ingredients to ensure against any deterioration in potency over the course of a product’s shelf life. The higher levels of omega-3 fatty acids in the fish oil product are not harmful according to laboratory scientists.

**Table 3: Fish Oil Product Testing Results**

Ingredient tested	Ingredient identified in product?	Amount of ingredient (milligrams)	Amount of ingredient advertised on label (milligrams per serving)
Fish oil (omega-3 fatty acids)	Yes	More than label amount (650–680)	600

Source: GAO analysis of testing data. | GAO-19-23R

**Trace Amounts of Contaminants Were Found in Selected Supplement Products but at Levels Considered Safe**

Trace amounts of heavy-metal contaminants were identified in supplement products tested, but the contaminant levels fell below health safety thresholds.<sup>23</sup> For all samples of the three selected products, we asked laboratory scientists to test for the presence of five heavy-metal contaminants known to be hazardous to health. The testing did not detect any of the contaminants at unsafe levels (see table 4). Specifically, the testing identified trace amounts of chromium in all three products, trace amounts of arsenic in the *Ginkgo biloba* and multi-ingredient memory supplement products, and trace amounts of lead in the multi-ingredient memory supplement product.

**Table 4: Contaminants Found in Selected Dietary Supplement Products**

Contaminant	Fish oil product	<i>Ginkgo biloba</i> product	Multi-ingredient memory supplement product
Arsenic	None detected (ND)	Trace amount	Trace amount
Cadmium	ND	ND	ND
Chromium	Trace amount	Trace amount	Trace amount
Lead	ND	ND	Trace amount
Mercury	ND	ND	ND

Source: GAO analysis of testing data. | GAO-19-23R

The laboratory also identified trace amounts of PCBs in fish oil product samples, but these were also at levels considered safe.

<sup>23</sup>Thresholds the laboratory tested to include criteria from the World Health Organization and the EPA, among others, according to the laboratory’s testing standards.



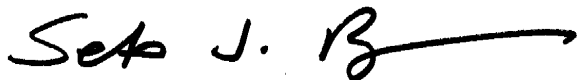
## Agency Comments

We provided a draft of this product to FDA, FTC, and the laboratory that tested the memory supplements included in our review, for comment. FDA and FTC told us that they had no formal comments on the draft report. FDA and the laboratory provided technical comments, which we incorporated as appropriate.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Commissioner of Food and Drugs, the Commissioner of Federal Trade, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions concerning this report, please contact Seto Bagdoyan at (202) 512-6722 or [bagdoyans@gao.gov](mailto:bagdoyans@gao.gov), or Timothy Persons at (202) 512-6412 or [personst@gao.gov](mailto:personst@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report were Latesha Love (Assistant Director); Celina Davidson (Analyst-in-Charge); Karen Howard, Ph.D., Chemist; Anna Maria Ortiz; Rebecca Parkhurst; and James Murphy.



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