



440 1st St. NW, Ste. 520, Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250

NEWS RELEASE

For Immediate Release
October 29, 2018

Contact: Justin Bartolomeo
(202) 789-4365
jbartolomeo@hdmk.org

NPA Reviews 10 Years of FDA Dietary Supplement GMP Compliance & Enforcement

Dietary Supplement Industry's Collaboration with Government Regulators Critical to Better Enforcement and Smarter Regulations

WASHINGTON, D.C. – Marking the 10th year of the Food and Drug Administration's (FDA) GMP program, the Natural Products Association (NPA) pledged to continue working collaboratively with its members and government regulators to develop smart regulations that lead to strong government enforcement and better consumer protection.

"The U.S. has the safest nutritional supplements in the world because of collaborative efforts between our industry and federal regulators," said Daniel Fabricant, Ph.D., president and CEO of NPA. "We are proud to have played a leading role developing these standards a decade ago and pledge to continue building upon this good work in the years to come."

NPA has always taken a leadership role in promoting quality standards and has developed proactive certification programs for that purpose. NPA was the first organization to offer a [third-party GMP certification program](#) for the manufacturing of dietary supplements and dietary ingredients. NPA also maintains a warning letter database for NPA members to view violations of GMPs.

Most Cited Part 111 Charge as a Function of Year

The chart below includes the top 10 most cited Part 111 citations issued for each year, with the top 5 citations for 2018 color coded for year-over-year comparison. Notable trends based on NPA's analysis of the data include:

- 21 CFR 111.103 – Beginning in 2015, there was a continual increase in the amount of times this has been cited in FDA-issued warning letters.
- 21 CFR 111.140 – This has shot up to the second most cited subheading of 2018. In the past, it never made it past the top 7 most cited.
- 21 CFR 111.70 – This has consistently been one of the most cited subheadings since 2010. While it is number 3 as of now in 2018, it is important to note that 103 and 140 have both managed to bypass it as a top cited subheading.
- 21 CFR 111.55 – This never subheading never even made it to the top 10 until 2017, now it is slowly becoming one of the top cited subheadings.
- 21 CFR 111.105 – This subheading has been slowly gaining traction since 2013, with the exception of it not even making the top 10 chart in 2016.
- 21 CFR 111.503 – The only other time this subheading made it to the top 10 was in 2012.
- 21 CFR 111.75 – Historically, this has been one of the most heavily cited subheadings (if not THE top cited subheading). Interestingly enough, it didn't even make it to the top 10 this year.

Most Cited Part 111	2010	2011	2012	2013	2014	2015	2016	2017	2018
1	75	70	70	70	75	70	70	70	103
2	70	75	75	75	70	260	103	103	140
3	73	205	205	205	103	255	75	75	70
4	210	210	255	260	260	75	95	255	55
5	260	260	260	210	205	103	255	55	105
6	27	255	103	255	255	205	260	105	503
7	35	140	210	103	140	105	205	140	553
8	77	83	553	105	105	210	210	205	65
9	123	103	27	140	553	73	73	65	83
10	140	455	503	55	210	95	105	553	535

27	Requirements that apply to equipment and utensils	140	Recordkeeping requirements for production and process control systems
35	Recordkeeping of equipment and utensils		
55	Requirements to implement a production and process control system	205	Requirement to establish a master manufacturing record for each formulation of a dietary supplement
65	Requirements for quality control operations when establishing a production and process control system	210	Requirements for the Master Manufacturing Record: What to include in master manufacturing record
70	Specifications to establish when establishing a production and process control system	255	Requirement to establish a batch production record
73	Responsibility for determining whether established specifications are met for establishing a production and process control system	260	Production and Process Control System: Requirements for the Batch Production Record - Batch record inclusion requirements
75	Determining if specifications are met for establishing a production and process control system	455	Requirements that apply to holding components, dietary supplements, packaging, and labels
77	Protocol for unmet established specifications for production and process control systems	503	Requirements for written procedures for dietary supplements
83	Requirements for reserve samples when establishing a production and process control system	535	Recordkeeping for returned dietary supplements
95	Recordkeeping when establishing a production & process control system	553	Written procedures for product complaints
103	Written procedures for production and process control systems		
105	Quality control personnel responsibilities for production and process control systems		
123	Quality control operations that are required for the master manufacturing record, the batch production record, and manufacturing operations		

NPA Educational Webinar

On October 30, 2018 NPA will host FDA officials and industry experts for an educational webinar examining the current trends in GMP compliance and enforcement for dietary supplements. Participants can register [online](#) by October 30, 2018. For more information about the webinar, please contact dnissinoff@npanational.org.



440 1st St. NW, Ste. 520, Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250

Natural Products Association

The **Natural Products Association (NPA)** is *the* trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or products for consumers. The Natural Products Association promotes good manufacturing practices as part of the growth and success of the industry. Founded in 1936, NPA represents approximately 1,000 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements and health/beauty aids. Visit www.npanational.org.