Bringing Your Product to Market
From the Vitamin Consultancy
Specifications, Testing and Samples Webinar
http://www.vitaminconsultancy.com/webinars.php

Checklist [mostly from GMPs Section IX]

1. Initial specifications list of proposed ingredients and the expected ratio/amount of each in the product.

2. Research and report on availability of ingredients and pricing.

3. Working specifications:

[1] Follow DSHEA "Supplement Box" format, with:

(1) estimate of size of capsules
(2) number of capsules in bottle
(3) serving directions

[2] List vitamins and minerals with DVs first (alphabetical order).
[3] For herbs, include the common name (may also include the scientific name).
[4] Specific ingredient purity and other detailed specifications should be included for each ingredient.
[5] "Other ingredients" to be specified.
[6] The Label Owner primary specification concerns are:

1. Specifications for final product (ingredients)
2. Specifications for label
3. Specification for finished labeling and packaging

4. Draft Label including:

[1] Central Panel with name, "Dietary Supplement" declaration and amount
[2] Right Panel with Supplement Box and contact information
[3] Left Panel with directions, disclosures and warnings

5. Submit Bid Package to contract manufacturer, including:

[1] Specifications
[2] Draft Label

[3] GMP contract terms and conditions [Ten conditions binding the manufacturer to abide by GMPs]

6. Select manufacturer and issue Purchase Order, including:

[1] Final Specifications
[2] Final Label
[3] GMP contract terms and conditions attached to PO

7. Testing:

[1] Test each ingredient before approving it for manufacturing
[2] Test each production batch to determine:

1. That the product meets the specifications for the product in 6 specific areas - 21 CFR 111.75(a) through (g)
2. That an expiration date, if any, is scientifically valid [Such a date is not required by FDA, so I do not recommend expiration dates]
3. Specific types of tests required - 21 CFR 111.75(h)(2)
4. Must test for: identity, purity, strength, composition, and the limits on types of contamination that may adulterate - 21 CFR 111.75(c) & (d)
5. Every finished batch must be tested - 21 CFR 111.75(c)

[3] The tests and examinations you use include at least one of the following (21 CFR 111.75(h)(2)):

1. Gross organoleptic analysis (21 CFR 111.75(h)(2)(i));
2. Macroscopic analysis (21 CFR 111.75(h)(2)(ii));
3. Microscopic analysis (21 CFR 111.75(h)(2)(iii));
4. Chemical analysis (21 CFR 111.75(h)(2)(iv)); or
5. Other scientifically valid methods (21 CFR 111.75(h)(2)(v)).

"...verify that a subset of finished dietary supplement batches (which you identify through a sound statistical sampling plan) meets product specifications..."

8. Samples and Shipping

[1] Obtain written approval of Quality Control Manager to release the product for shipping.
[2] Maintain samples of each batch in a locked cabinet, with indication of when the sample was taken.

9. Post Market FDA Notice:

Prepare Structure and Function Notice setting forth:
Claims
Ingredients
Label Copy
Sworn statement that the company has “substantiation” of claims on file.