

**AMENDMENT**

**OFFERED BY M**\_\_ . \_\_\_\_\_

**[Page/line numbers refer to OTCMONOGRAPH\_\_05, dated  
January 12, 2018]**

On page 56, after line 8, insert the following:

1 **SEC. 105. GOOD MANUFACTURING PRACTICES FOR COS-**  
2 **METICS.**

3 (a) IN GENERAL.—Chapter VI of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as  
5 amended by section 102, is further amended by adding  
6 at the end the following:

7 **“SEC. 604. GOOD MANUFACTURING PRACTICES FOR COS-**  
8 **METICS.**

9 “(a) IN GENERAL.—The Food and Drug Administra-  
10 tion shall review national and international standards for  
11 cosmetic good manufacturing practices that are in exist-  
12 ence on the date of enactment of the Cosmetic Safety En-  
13 hancement Act of 2018 and shall develop and implement,  
14 through regulations, United States standards consistent,  
15 to the extent the Food and Drug Administration deter-  
16 mines practicable and appropriate, with such national and  
17 international standards for cosmetic good manufacturing  
18 practices to ensure that requirements of this chapter with

1 respect to the manufacture of cosmetic products are in  
2 harmony.

3 “(b) TIMEFRAME.—The Food and Drug Administra-  
4 tion shall publish a proposed rule described in subsection  
5 (a) not later than 18 months after the date of enactment  
6 of the Cosmetic Safety Enhancement Act of 2018 and  
7 shall publish a final such rule not later than 3 years after  
8 such date of enactment.”.

9 (b) EFFECTIVE DATE FOR COSMETIC MANUFACTUR-  
10 ERS.—

11 (1) LARGE BUSINESSES.—For businesses of a  
12 size greater than the Small Business Administra-  
13 tion’s standard for a small business, section 604 of  
14 the Federal Food, Drug, and Cosmetic Act (as  
15 added by subsection (a)) shall take effect beginning  
16 180 days after the date on which the Food and  
17 Drug Administration publishes the final rule de-  
18 scribed in subsection (a).

19 (2) SMALL BUSINESSES.—For businesses of a  
20 size that meets the Small Business Administration’s  
21 standard for a small business, section 604 of the  
22 Federal Food, Drug, and Cosmetic Act (as added by  
23 subsection (a)) shall take effect beginning 2 years  
24 after the date the Food and Drug Administration

1 makes effective the final rule described in subsection  
2 (a).

3 (c) ENFORCEMENT.—Section 601 of Chapter VI of  
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 361) is amended by adding at the end the following:  
6 “(f) If the methods used in, or the facilities or con-  
7 trols used for, its manufacture, processing, packing, or  
8 holding do not conform to current good manufacturing  
9 practice, as prescribed by the Food and Drug Administra-  
10 tion.”.

