The US FDA has published an update in the Federal Register which leads to an update to the Code of Federal Regulations (21 CFR Parts 600, 610 and 680) with respect to the Sterility Test.

The key changes are (as detailed in the Register):

- Eliminates specified sterility test methods, culture media formulae (or formulation), and culture media test requirements;
- Eliminates specified membrane filtration procedure requirements for certain products;
- Eliminates specified sterility test requirements for most bulk material;
- Modifies the repeat sterility test requirements, so that repeat tests will occur only once for each lot. These repeat tests are limited to situations when the quality control unit conclusively determines, after conducting an investigation upon detection of viable microbial contamination during the initial test of the lot, that the contamination is the result of laboratory error or faulty materials used in conducting the sterility test;
- Replaces the storage and maintenance requirements for cultures of test organisms used to determine the ‘‘growth-promoting qualities’’ of culture media with: (1) Validation requirements specifying that any sterility test used is able to consistently detect the presence of viable contaminating microorganisms and (2) verification of ‘‘growth promoting properties’’ or microorganism-detection capabilities of test and test components;
- Replaces the sample size or amount requirement with a requirement that the sample be appropriate to the material being tested;
- Replaces the Interpretation of test results section under § 610.12(c) with a requirement that manufacturers establish, implement, and follow written procedures for sterility testing that describe, at a minimum, the test method used, the method of sampling, and the written specifications for acceptance or rejection of each lot;
- Simplifies and clarifies the Exceptions section under § 610.12(h); and
- Identifies the Director of CDER as one of the two Center directors authorized to grant an exemption under the exception provision at § 610.12(h)(2). In the proposed rule, the Center for Devices and Radiological Health was erroneously identified in this exception, instead of the Center for Drug Evaluation and Research.
- Revises the definition of the term ‘‘sterility’’ under § 600.3(q); and
- Eliminates certain exceptions for allergenic products related to sterility testing under § 680.3(c).

The update is detailed in Volume 77, No.86 (issued Thursday May 3).

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