U.S. FOOD & DRUG ADMINISTRATION

Changes that Affect Compounders as of March 23, 2020

A change to the law will impact compounding of certain products beginning on March 23, 2020. On that date, biological products that were approved under the Federal Food, Drug, and Cosmetic (FD&C) Act will transition to being licensed under the Public Health Service (PHS) Act. Beginning on March 23, these transitioning biological products will not be eligible for the exemptions for compounded drugs under sections 503A and 503B of the FD&C Act.

The agency posted a preliminary list of approved biological products that will transition. Outsourcing facilities have recently reported using four bulk drug substances that are affected by the transition: human chorionic gonadotropin, hyaluronidase, follicle stimulating hormone (FSH or urofollitropin) and menotropins. One of these products – hyaluronidase – was on category 1 of the list of substances under our 503B bulks interim policy. As of March 23, this substance will be removed from category 1.

Although these transitioning biological products will not be eligible for the exemptions in sections 503A and 503B, the agency's guidance, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application, explains the conditions under which we do not intend to take action when certain biological products are mixed, diluted, or repackaged in a manner not described in their approved labeling.

Background:

The Biologics Price Competition and Innovation (BPCI) Act of 2009 created an abbreviated licensure pathway under the PHS Act for biological products that are demonstrated to be biosimilar to, or interchangeable with, an FDA-approved biological product. This pathway was established as a way to provide more treatment options, increase access to lifesaving medications, and potentially lower health care costs through competition.

A provision in the BPCI Act also requires that, on March 23, 2020 (10 years after enactment), an approved marketing application for a biological product under section 505 of the FD&C Act shall be deemed to be a license for the biological product (i.e., an approved biologics license application or BLA) under section 351 of the PHS Act.

See deemed to be a license and changes that affect compounding as of March 23, 2020 for more information.

Please contact FDA's compounding team at compounding@fda.hhs.gov with any questions.

For more information, please visit FDA's Human Drug Compounding web site.

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