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FDA Invites Compounding Outsourcing Facilities' Comments to Understand Industry Challenges and Opportunities

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On July 29, 2019, the Food and Drug Administration (FDA) published a notice to the Federal Register (**84 Fed. Reg. 36609**). The notice invites comments on information collected in connection with FDA research by obtaining information from pharmacists and other management at outsourcing facilities as well as related compounding businesses. The collected information will support a comprehensive analysis of the outsourcing facility sector with hopes to inform future FDA work in this area.

Background

Drug compounding is the practice of combining, mixing, or altering ingredients of a drug to create a medication tailored to the needs of an individual patient. However, compounded drugs are not FDA-approved and do not undergo premarket review by FDA for safety, efficacy, and quality. Therefore, while they can meet important medical needs, they can also present risks to patients. To combat these risks, federal law places conditions on compounding designed to protect the public health.

The Drug Quality and Security Act of 2013 (DSQA) created “outsourcing facilities,” or 503B facilities that engage in the compounding of sterile drugs by complying with the current Good Manufacturing Practice requirements, are inspected by FDA, and meet certain other conditions required by FDA. Outsourcing facilities supposedly offer a more reliable supply of compounded drugs needed in bulk by hospitals, clinics, and other providers. Since the creation of DSQA and outsourcing facilities, this industry remains relatively small due to growth and market challenges, as well as continuing concerns over the quality and safety of such facilities identified during FDA inspections. To assist the outsourcing industry in meeting its intended function, FDA aims to implement several initiatives to address these challenges and support industry advancement.

FDA’s First Initiative

One such FDA initiative includes conducting in-depth research and analysis to better understand the challenges and opportunities encountered by the outsourcing facility sector. Some examples of those challenges and opportunities include: (i) operational barriers and opportunities related to the outsourcing facility market and business viability; (ii) knowledge and operational barriers and opportunities related to compliance with federal policies and good quality drug production; and (iii) barriers and opportunities related to outsourcing facility interactions with FDA.

FDA intends to use the results of this research to develop a comprehensive understanding of the outsourcing facility sector, its challenges, and opportunities for its advancement. FDA desires to be able to identify gaps, operational barriers, and future approaches to communication, education, and training.

FDA's July 29 notice aims to engage pharmacists, staff, and management from outsourcing facilities and related compounding businesses. Specifically, FDA hopes to solicit comments on the following topics:

1. Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;
2. The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Ways to enhance the quality, utility, and clarity of the information to be collected; and

4. Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The FDA invites public comment for 60 days in response to the notice. Comments will close on September 27, 2019. Stay tuned for more compounding updates.

Authors