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ALERTS

Food, Drug & Device Law Alert - FDA Issues Draft Guidance On Humanitarian Device Exemption

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The FDA Safety and Innovation Act (FDASIA), enacted in July 2012, amended the Food, Drug & Cosmetic Act (FDC Act) to allow the makers of Humanitarian Use Devices (HUDs) to make a profit in certain circumstances. The FDA has recently released a draft guidance in question and answer format addressing the Humanitarian Device Exemption (HDE), including the circumstances in which the manufacturer can make a profit.

As amended by FDASIA, the FDC Act now allows a manufacturer to sell an HUD for profit after receiving HDE approval, if the device meets the following criteria:

1. The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which Indianapolis (IND) the disease or condition occurs; or
2. The device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

According to the draft guidance, a pediatric population includes anyone who has not yet reached their 22nd birthday. Further, “FDA does not consider economic factors (such as the costs associated with conducting a clinical investigation) as a basis for being ‘impossible’ or ‘highly impracticable.’” Rather, “FDA may determine that the development of a particular device is ‘impossible’ or ‘highly impracticable’ in pediatric patients if it is intended to treat a disease or condition that has a pediatric annual incidence that is so small or if the pediatric population is so geographically dispersed to prevent sufficient patient recruitment in the pediatric population for a clinical investigation.”

The draft guidance discusses the two-step process necessary to obtain an HDE approval. First, an HDE applicant must submit a HUD designation request to OOPD and receive HUD designation. In the review of a HUD designation request, FDA will determine whether the device is for a rare disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

After the applicant receives the HUD determination, the second step is for the applicant to seek premarket approval for an exemption from the

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effectiveness requirement for devices under the FDC Act. FDA will approve the HDE criteria if, among other criteria, it determines that "the HUD will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use while taking into account the probable risks and benefits of currently available devices or alternative forms of treatment."

The thirty-one page draft guidance addresses other aspects of exemption as well, and a copy may be found here.

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