Journal of Refractive Surgery

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Volume 11 (5) * September/October 1995 * News

FDA Takes on Maker of "Homemade" Excimer Lasers

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As the number of US ophthalmologists using "homemade" excimer lasers to perform refractive surgery continues to grow, the US Food and Drug Administration (FDA) is taking action against the laser engineer thought responsible for making most of these "custom" instruments.

Ed Sullivan, doing business as ExSull, Drexel Hill, Pa, has been put on notice by the FDA that the agency regards him "clearly as a manufacturer with multiple manufacturing sites" subject to FDA rules and regulations and, if he makes another one of these excimer lasers "which are unapproved devices," he will be in violation of the federal Food, Drug and Cosmetics Act and subject to legal penalties, according to top-ranking FDA officials within the national Division of Enforcement.

Sullivan was informed in mid-May in a teleconference with top officials from both the FDA Division of Enforcement national headquarters and the Philadelphia District Compliance Office that it is the FDA's position that Sullivan's excimer lasers are not "custom devices" and not exempt from regulation as a physician's practice-