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WARNING LETTER
VIA EXPRESS MAIL

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

MAR 21

Mr. Olaf Morcher
President
Morcher GmbH
Kapuzinerweg
D70374 Stuttgart
Wurttemberg-Baden,
GERMANY

Dear Mr. Morcher

It has come to our attention that your firm is involved in the manufacturing and distribution of aniridia implants being imported into the U.S. As you are aware, this product is considered to be a medical device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Our records indicate that Morcher has not received FDA approval to market and distribute aniridia implants.

Therefore, this device is misbranded within the meaning of Section 502(o) in that a notice or other information respecting the device was not provided to the FDA as required by Section 510(k) [21 U.S.C. 360(k)]. Furthermore, the devices manufactured by your firm are adulterated within the meaning of Section 501(f)(1)(B) in that they are Class III devices under Section 513(f) and do not have an approved application for premarket approval in effect pursuant to Section 515(a) and are not exempt from such requirements in that you do not have an approved application for investigational device exemption under Section 520(g).

Given the serious nature of these violations of the Act, the distribution of unapproved aniridia devices manufactured by your firm, may be detained upon entry into U.S. until these violations are corrected.

In order to remove your device from this detention, it will be necessary for you to obtain Agency approval to market these devices lawfully. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

FDA is aware that many doctors are seeking to use implants for iris reconstruction ("aniridia implants") in the United States (U.S.). Currently in the U.S., there are no implantable devices approved to treat congenital aniridia or to otherwise reconstruct the iris because of trauma or other reasons. We are writing to you to clarify the regulatory status of these devices and to offer our opinions on ways that you could legally distribute these products in the US.

Status/ Investigational Device Exemption

There are no implantable prostheses for permanent treatment of aniridia currently approved by the Food and Drug Administration (FDA). Aniridia contact lenses for temporary treatment are available in the US. FDA is aware of intraocular lenses (IOLs) and capsular tension rings that have been modified to provide a diaphragmatic, artificial iris. Because these aniridia implants are Class III devices, and use of the devices in the US is considered investigational, studies of the devices require a FDA-approved Investigational Device Exemption (IDE) application.

For most patients, placement of a modified IOL or ring appears to be a solution to alleviate the debilitating symptoms many patients' experience as a result of their condition. Further, the importance of alleviation of these symptoms may outweigh some potential risks. Although preclinical safety data will be necessary in an IDE, it may be possible for FDA to waive some of the typical testing, as described in FDA's guidance document for intraocular lenses.

Humanitarian Device Exemption (HDE)

Because aniridia is a rare condition, we believe that obtaining a Humanitarian Device Exemption (see section 520(m) of the Federal Food, Drug, and Cosmetic Act) may be the least burdensome path to marketing in the US. A Premarket Approval Application (PMA) is also possible.

The HDE provision of the statute allows FDA to exempt from effectiveness requirements devices intended to treat a rare (4000 cases per year in U.S.) condition for which there are no comparable devices to treat the condition.

Section 520(m) states that FDA must find that "the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available device or alternative forms of treatment." It should be noted, however, that if a PMA were to be approved for an aniridia implant, an HDE would no longer be viable.

FDA would expect that an HDE with a limited case series of subjects may provide the evidence needed for approval. Presentation of at least 30 medical histories from aniridia implant subjects is suggested. We believe that if a standard report was distributed to surgeons to record their postoperative findings under an IDE, these data could be readily obtained.

In order to pursue an HDE, you would need to get a Humanitarian Use Device designation from FDA's Office of Orphan Products Development (OPD). Dr. Debra Lewis in that office should be contacted to help with that process. She can be reached at (301) 827-0059. The OPD also offers grants for studying rare disorders and for providing development funding for devices for rare conditions. Unfortunately for 2001, proposals must have been received by OPD by March 15, 2001; grant funds would then become available September 30, 2001. A similar schedule is followed yearly.

Premarket Approval Application

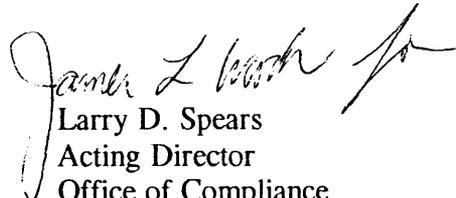
A premarket approval application would be another option available to a sponsor to distribute aniridia IOLs or aniridia rings. Again, we believe that a limited case series would provide the appropriate clinical data to support a PMA. Showing of effectiveness is *not* exempted as in HDEs, but we believe effectiveness could be easily demonstrated.

FDA is concerned that patients with aniridia are in need of treatment, yet device availability is uncertain. We hope that you will work with the Agency in development of the necessary information to bring these devices to market in the U.S.

Please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations.

If you have any questions, please contact Mr. Ronald L. Swann, at (301) 594-4613 ext. 109 or FAX (301) 594-4638 or write to the letterhead address. If you wish to explore an IDE, HDE, or PMA, please contact Donna R. Lochner at (301) 594-2053.

Sincerely yours,


Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health