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### FDA Statement On Lipo-Dissolve

The FDA is aware of the practice of using Lipo-Dissolve. Lipo-Dissolve is not FDA approved for any use. In fact, there are no FDA-approved drugs with an indication to dissolve fat . FDA cannot assure the safety and efficacy of these types of drugs. These are unapproved drugs for unapproved uses and FDA cannot guarantee consumers' safety.

It is our understanding that some physicians may be using compounded drugs in "lipodissolve" procedures. In virtually all cases, FDA regards compounded drugs as unapproved drugs, meaning - compounded drugs are not FDA-approved drugs.

The use of compounded drugs is not considered "off-label" use. If a physician uses an FDA-approved drug for an indication not in the approved labeling this is considered "off-label" use. FDA approval of a drug includes approved labeling for use, and means that the FDA has evaluated the safety and efficacy of a drug for a specific use and population. Once approved, a drug may be prescribed by a licensed physician for a use that, based on the physician's professional opinion, is appropriate. This prescribing is considered part of the practice of medicine, but it is expected that the physician is well-informed about the product and that the "off-label" use is based on sound scientific rationale and adequate medical evidence.

We are not aware of any phosphatidylcholine injectable products or sodium deoxycholate injectable products that could be used "off label" in "lipodissolve" procedures.