progress reports must be submitted annually in accordance with applicable IDE regulations. The sponsor of a Treatment IDE is responsible for submitting all other reports required under 21 CFR 812.150; such as unanticipated adverse device effects and final reports. The reports are submitted as supplements to the original IDE application.

8.9 OFF-LABEL USE OF MARKETED DRUGS, BIOLOGICS, AND DEVICES

At the time that the FDA approves a new drug, biologic, or device for marketing, it also specifies the indications, patient groups, and formulation under which the drug, biologic, or device may be used. Any variance from these approved specifications constitutes “off-label” usage.

If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgement. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an IND or IDE to the FDA or review by the IRB.

8.10 FDA CONTACTS

- For drug products: Drug Information Branch at (301) 796-3400; druginfo@fda.hhs.gov; Questions about whether a product is subject to IND regulations: call (301)796-3400
- For biological products: (301) 827-2000; Questions about whether a product is subject to IND regulations: call 301-827-2000
- For device products: visit the webpage: Division of Industry and Consumer Education (DICE); DICE@fda.hhs.gov
- For physicians seeking information on Expanded Access/ Emergency Use visit this FDA webpage.
- FDA Emergency Call Center, telephone: 866-300-4374 after 4:30 pm EST weekdays and all day on weekends.