

much of the CMC information required by 21 CFR 312.23(a)(7) as is available. However, the FDA recognizes that a sponsor may not be able to obtain all of the CMC information required by 21 CFR 312.23(a)(7) for a non-U.S.-licensed comparator product for which it is not the manufacturer. In these circumstances, the sponsor can request that the FDA waive the requirement for complete CMC information on the non-U.S.-licensed comparator product (21 CFR 312.10). The IND must include, as part of the waiver request, at least one of the following:

- A sufficient explanation why compliance with the complete requirements of 21 CFR 312.23(a)(7) is unnecessary or cannot be achieved,
- Information that will satisfy the purpose of the requirement by helping to ensure that the investigational drug will have the proper identity, strength, quality, and purity, or
- Other information justifying a waiver.

Information that is relevant to whether the investigational drug will have the proper identity, strength, quality, and purity may include, for example, information indicating whether the investigational drug has been licensed by a regulatory authority that has similar scientific and regulatory standards as the FDA (e.g., International Conference on Harmonisation [ICH] countries). This should include, to the extent possible, summary approval information and current product labeling made public by the foreign regulatory authority. In addition, a sponsor should also provide information on the conditions and containers that will be used to transport the drug product to the U.S. clinical site(s) and information on the relabeling and repackaging operations that will be used to relabel the drug product vials for investigational use. (This should include information on how exposure of the product to light and temperature conditions outside of the recommended storage conditions will be prevented. A risk assessment on the impact the relabeling operations may have on drug product stability should also be included.)

The sponsor should consult with the appropriate the FDA review division regarding the CMC information necessary to support the proposed clinical trial.

As applicable to all investigational drugs, the FDA reminds sponsors that the investigator brochure (IB) for studies to be conducted under the IND should be carefully prepared to ensure that it is not misleading, erroneous, or materially incomplete, which can be a basis for a clinical hold (see 21 CFR 312.42(b)