GUIDANCE DOCUMENT

Devices Used to Process Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

Guidance for Industry and FDA Staff

July 2007

Final

Issued by: Office of the Commissioner, Office of Clinical Policy and Programs, Office of Combination Products

For questions regarding this document, contact:
Office of Combination Products
301-796-8930

Additional copies are available from:
Office of Combination Products
Food and Drug Administration
WO32, Hub/Mail Room #5129,
10903 New Hampshire Avenue,
Silver Spring, MD 20993
301-796-8930
(Fax) 301-847-8619
http://www.fda.gov/CombinationProducts/default.htm
combination@fda.gov

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

TABLE OF CONTENTS

Purpose

This guidance is intended to improve the transparency of FDA’s jurisdictional determinations by providing detailed information about the classification and assignment of certain products. The jurisdictional information contained in this guidance document may be based on a past decision made in response to a Request for Designation submitted pursuant to 21 CFR Part 3, or in response to a request for an informal jurisdictional determination. FDA’s Office of Combination Products (OCP) issues jurisdictional updates on selected classes of products on an ongoing basis. OCP selects products to be the subject of jurisdictional updates based on its perception of the current level of interest in the jurisdictional issue, the extent to which the class of products can be clearly described, the extent to which the existence and description of the class of products has been made public, and related factors.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

Jurisdictional Information

FDA has received requests for designation (RFDs) for devices intended to process human cells, tissues, or cellular and tissue-based products (HCT/Ps) at the point of care. A frequently asked question in these RFDs has been whether the device should be assigned to the Center for Biologics Evaluation and Research (CBER) or the Center for Devices and Radiological Health (CDRH) for review and regulation.

Devices intended to process HCT/Ps ex vivo to create a therapeutic article, that is, products where the intended therapeutic effect is mediated by the biologic output of the device, have been assigned to CBER. For example, cell sorters used at the point of care to isolate and/or concentrate autologous stem cells or hematopoietic progenitor cells for in vivo use have been assigned to CBER for review under the device provisions of the Federal Food, Drug, and Cosmetic Act (the Act), or the Public Health Service (PHS) Act. Similarly, devices that process autologous blood or tissue to produce a new HCT/P (e.g., a tissue engineered, live cell construct) at the point of care, for direct re-administration to that patient have also been assigned to CBER for review. CBER should be consulted for further information about the regulatory pathway for such products, including information on the review and regulation of the HCT/P.[1]

In contrast, cell sorters designed to isolate or concentrate a specific cell population have been assigned to CDRH for review under the device provisions of the Act when the sorted cells are intended only for in vitro diagnostic use. The labeling of these products typically limits them to in vitro diagnostic use and the output material is not evaluated for suitability for readministration.

For further information

For an informal determination whether a particular device will be assigned to CBER or CDRH contact:

Center for Biologics Evaluation and Research (CBER) Center Contact:
Sheryl Lard Whiteford, Ph.D.
Email: CBERProductJurisdiction@fda.hhs.gov
Telephone: 240-402-7912

or

Center for Devices and Radiological Health (CDRH) Center Contact:
James Bertram, PhD.
E-mail: CDRHProductJurisdiction@fda.hhs.gov
Telephone: 301-796-9588

or

The Office of Combination Products may also be contacted at
Food and Drug Administration
WO32, Hub/Mail Room #5129,
10903 New Hampshire Avenue,
Silver Spring, MD 20993
301-796-8930
Email: combination@fda.gov

A formal determination of the assignment of a particular product may be made through the RFD process. Further information about the RFD process is available at 21 CFR Part 3 and in the document "Guidance for Industry and FDA: How to Write a Request for Designation (RFD)," available at www.fda.gov/oc/combination/. It is recommended that sponsors call OCP at 301-796-8930 to discuss their particular situation before submitting an RFD.

OCP is always available as a resource to you. We encourage you to contact OCP if you have any questions about the jurisdiction of your product.

Footnote:

1 For example, see Guidance for Industry, Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs) at http://www.fda.gov/cber/gdlns/pbsc.htm.