

**Notice Regarding Expiration Date on Form FDA 3356  
June 6, 2017**

Form FDA 3356 is currently used by establishments to register and list their products in accordance with FDA regulations (21 CFR 1271.21). The expiration date that appears in the upper right corner of form 3356 is a date the agency uses to manage its forms, and does not relate to an establishment's registration expiration. As explained on FDA's [Basics for Industry webpage](#), on occasion, forms currently in use by FDA reach their expiration dates. FDA staff work with OMB to update and renew the expired form(s) for posting on the agency's web site for [FDA Forms](#). The forms posted on this site may be used during this time of update and renewal.

**Additional Background Information**

The Paperwork Reduction Act (PRA) of 1995 requires U.S. federal government agencies to obtain Office of Management and Budget (OMB) approval before requesting or collecting most types of information from the public. Forms used by government to collect such information are approved and include an OMB assigned control number with an expiration date.

The PRA requirements apply to the collection of HCT/P establishment registration and listing information. On Form FDA 3356, the OMB control number and the expiration date of the form appear in the upper right corner of the [first page](#). This expiration date **does not** reflect the expiration date of an HCT/P establishment's registration and listing with the FDA. On Form FDA 3356, the FDA registration validation date is listed in the "Validation – For FDA Use Only" box, in the upper right corner and it is valid for that year.

**Electronic Human Cell and Tissue Establishment Registration (eHCTERS)**

Members of the public may visit [Human Cell and Tissue Establishment Registration \(HCTERS\) Public Query](#) web page to obtain the most recent, up-to-date information about an establishment's annual registration. For example, if the last annual registration year is listed as 2017, it means that the establishment's registration is valid through December 31, 2017. If the query's report for an establishment shows a year earlier than 2017, the registration is only valid for the year indicated.

On August 31, 2016, FDA published a final rule titled, "[Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs](#)." There are a few changes in this new rule that apply to HCT/Ps, including the requirement for establishments to use the electronic registration system for submission of registration information, unless waived in certain circumstances. The effective date for this new rule was November 29, 2016, and the compliance deadline is set for one year after the effective date. Therefore, after November 29, 2017, Form FDA 3356 will no longer be used. The Agency is currently in the process of modifying the electronic system for human cell and tissue establishment registration and listing and will be communicating changes to all stakeholders.

Submit questions to the Tissue Registration Coordinator ([tissuereg@fda.hhs.gov](mailto:tissuereg@fda.hhs.gov)).