U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

ATTENTION

Returning FDA Industry Systems
Device Registration and Listing Module Users

Effective July 1, 2016

The Device Registration and Listing Module of the FDA Unified Registration and Listing System (FURLS) has been modernized with a new look and feel to provide users with the most productive and expeditious experience possible. While the layout and design have changed, users will notice that all the information required and processes remain the same. All existing capabilities are available under the new and improved format.

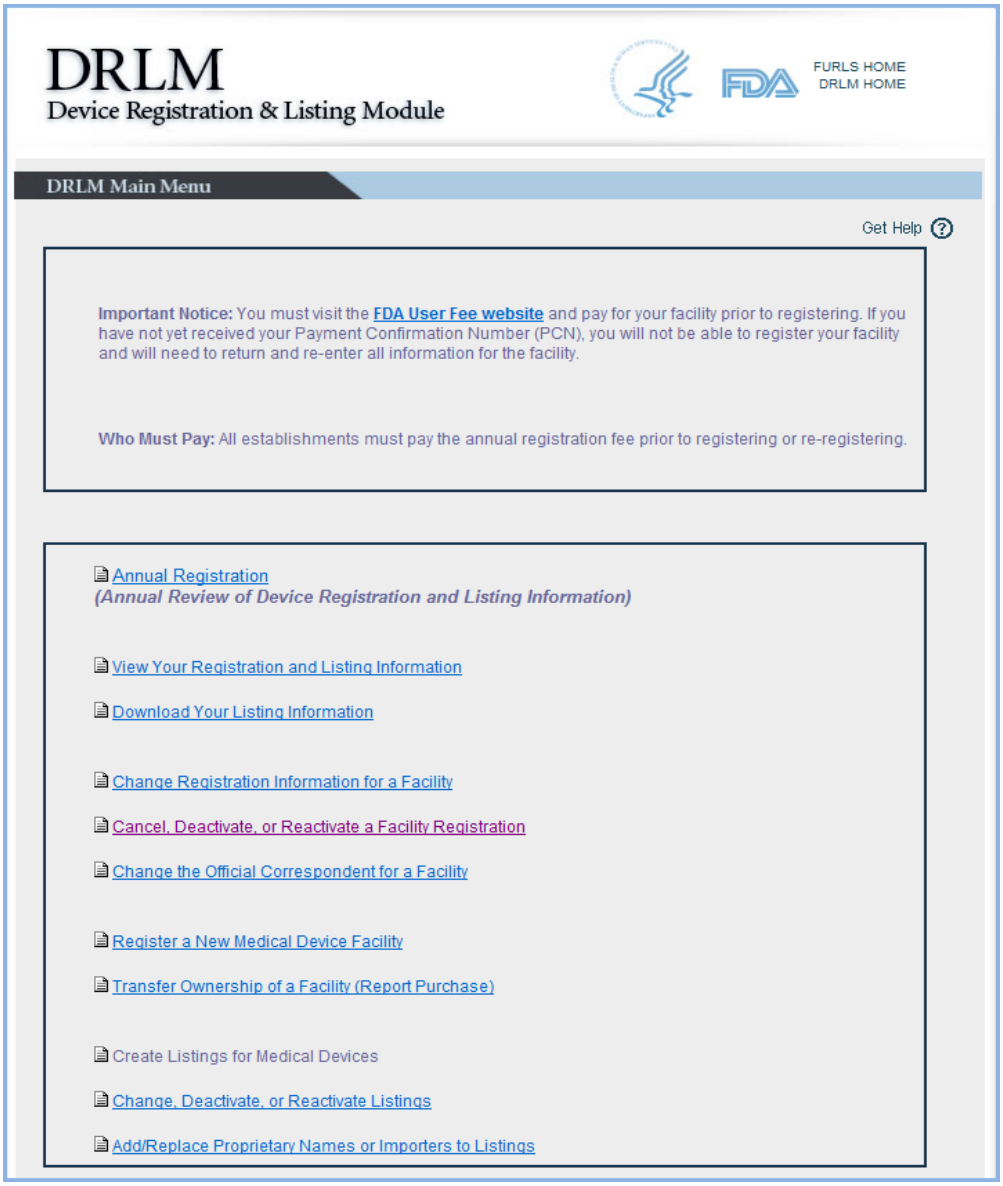
Users will continue to access DRLM or any of the other FURLS systems via the FDA Industry Systems home page. Please contact the FURLS Help Desk with any questions regarding the updated format (reglist@cdrh.fda.gov or call 301-796-7400, Option 1).

The sections below provide brief examples of the following capabilities:

Welcome/Home Page

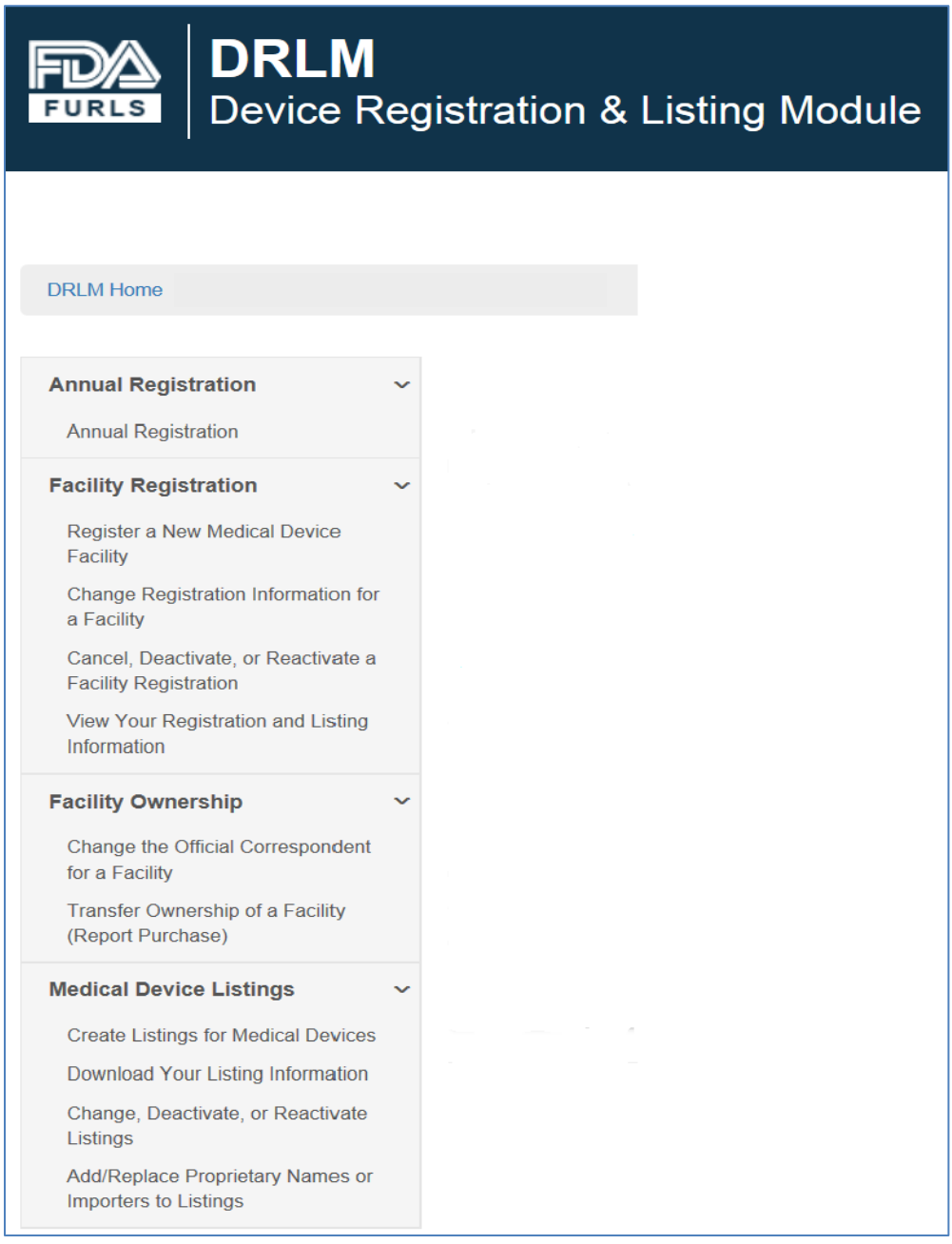
On the DRLM Welcome/Home page, users can complete any DRLM activity by choosing the appropriate Main Menu option from the left navigation bar rather than a menu on a separate screen.

Existing DRLM 'Main Menu' interface: *



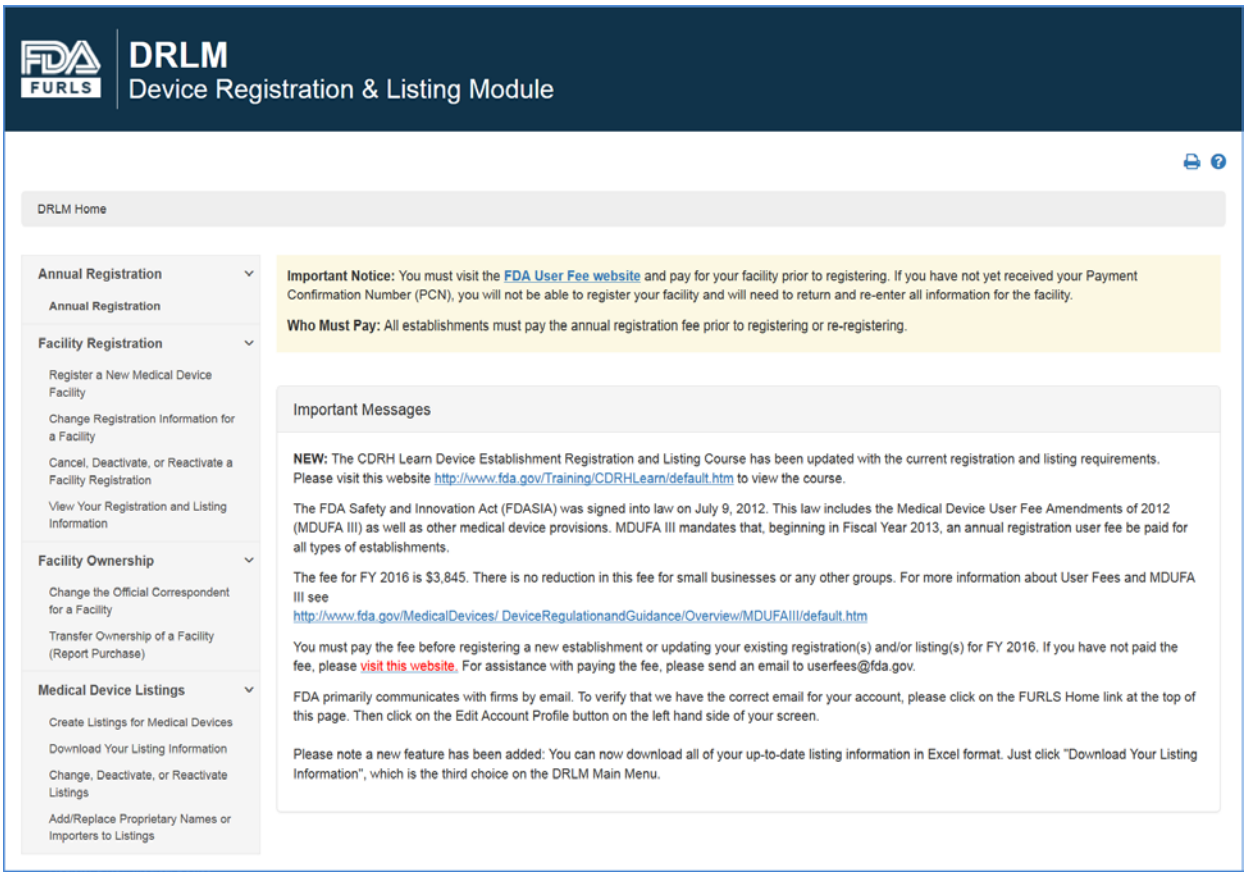
*All 'Existing' pages are valid till June 30, 2016

Updated DRLM ‘Main Menu’ Options on the Left Navigation Bar:



The screen captures displayed should be considered representative of the final changes

Updated DRLM 'Home Page' interface:



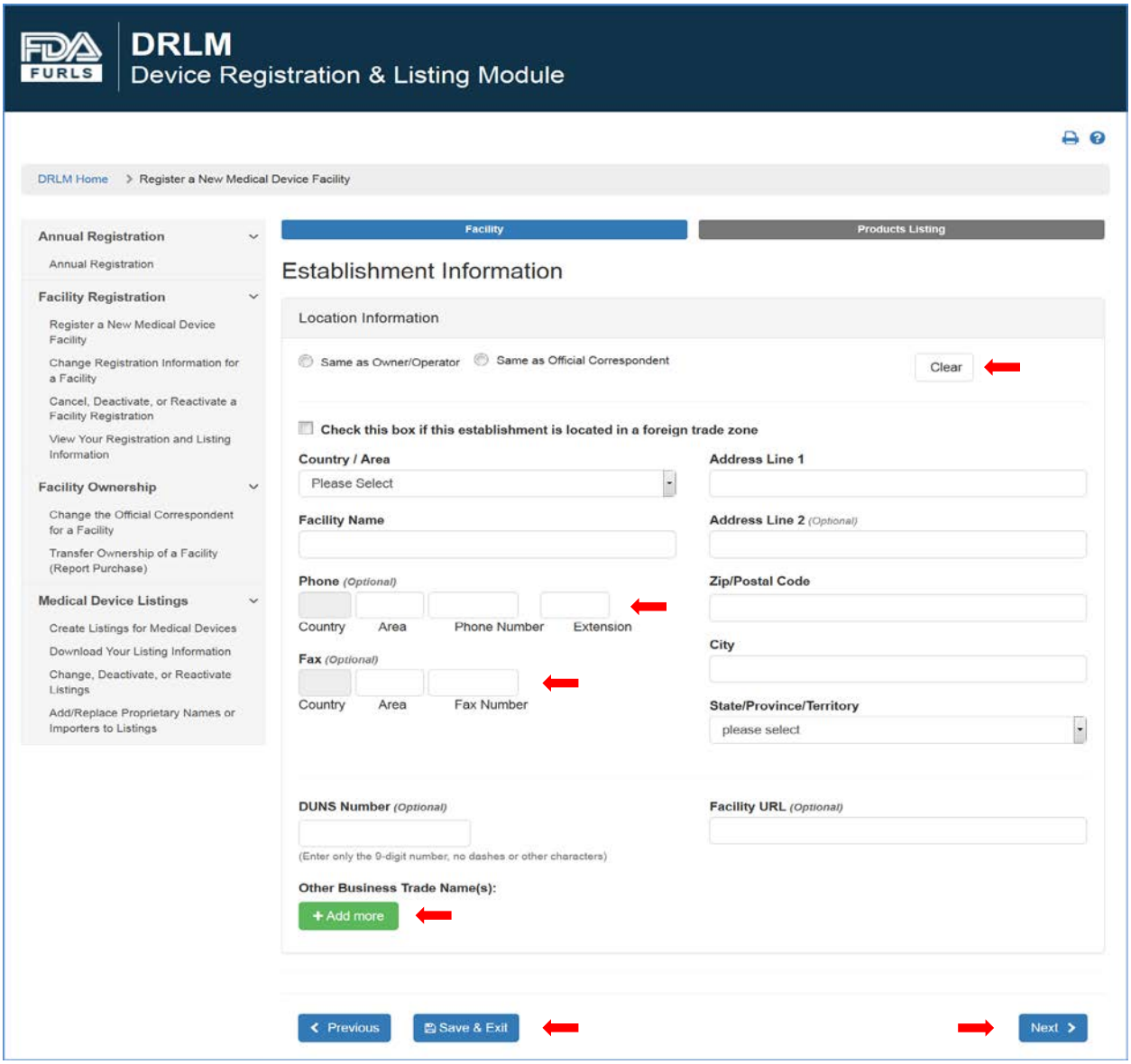
The screen captures displayed should be considered representative of the final changes.

Entering Address Information

When registering a device facility or updating address information for an existing registration, users will notice certain enhancements that apply uniformly among various elements (e.g., data fields and navigational buttons). All design updates were implemented to enhance user experiences and ensure efficient usability throughout the application.

Existing DRLM 'Address Information' interface:

Updated DRLM 'Address Information' interface:



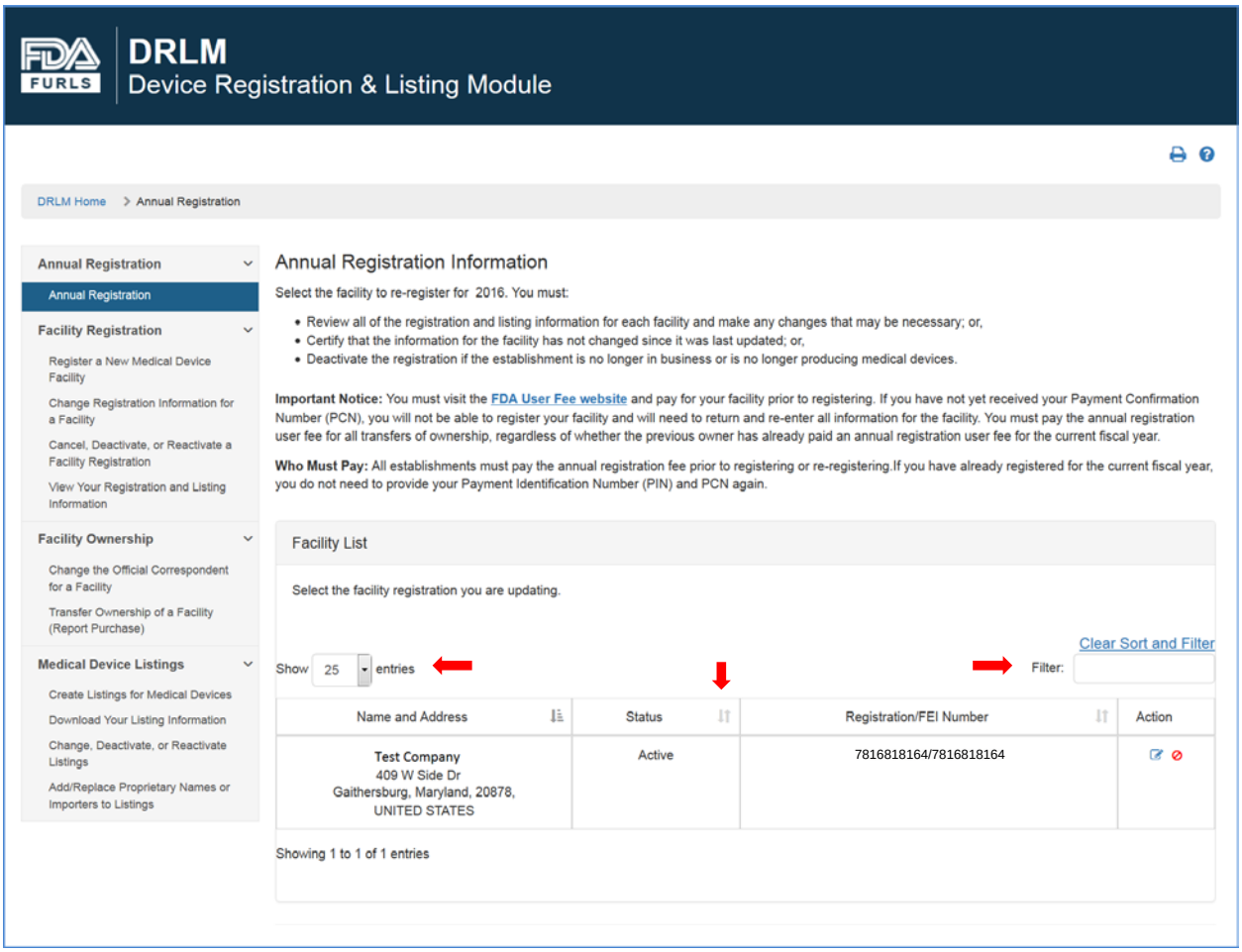
The screen captures displayed should be considered representative of the final changes.

Making Selections in Lists (Sort and Filter)

As seen in the Annual Registration and Add New Product option, DRLM now contains unique data tables that provide advanced features such as a wildcard filter option that filters records within the search results. It also features a dropdown selection to allow users to select how many results should be displayed on the page.

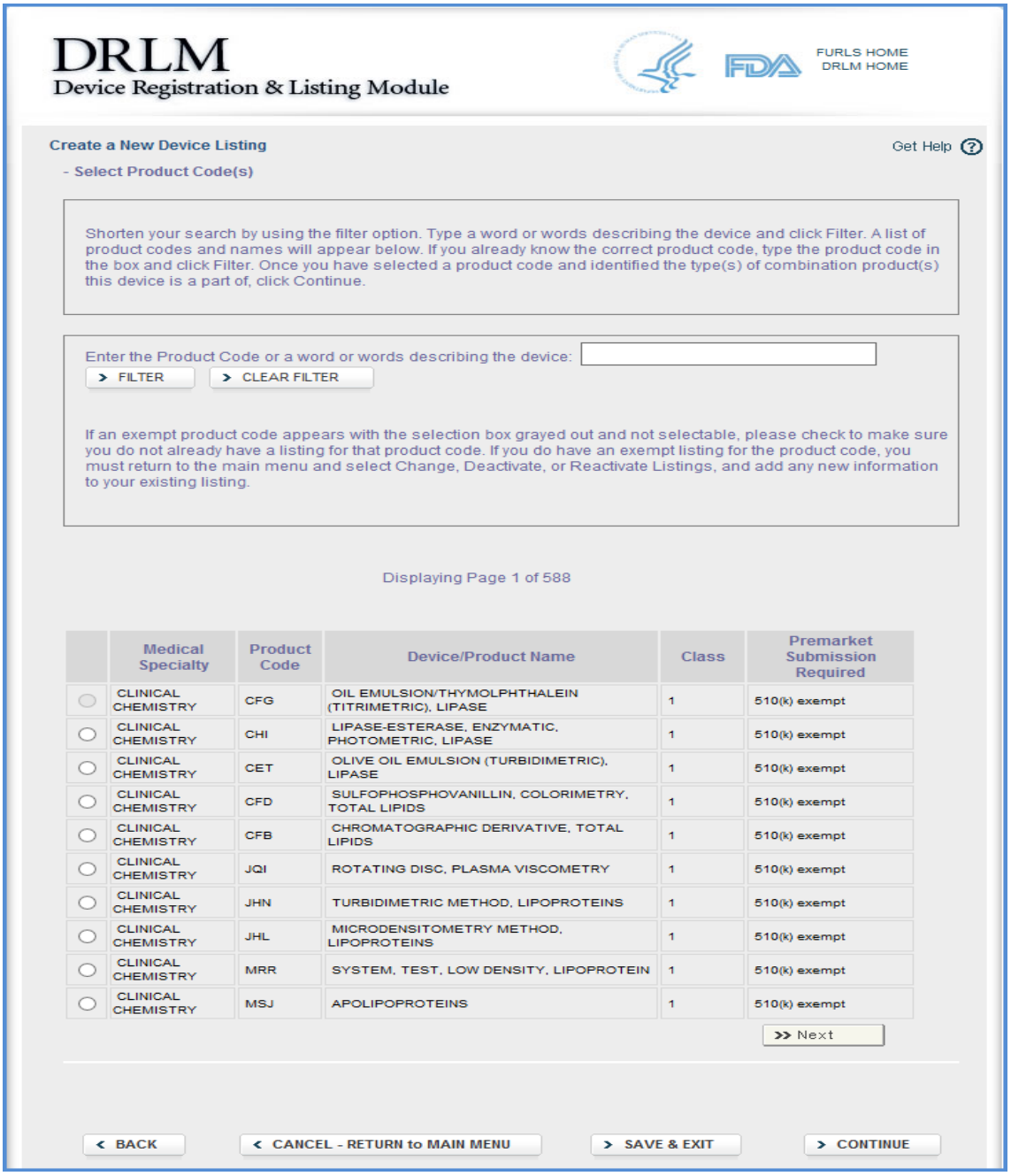
Existing DRLM 'Annual Registration' interface:

Updated DRLM 'Annual Registration' interface:



The screen captures displayed should be considered representative of the final changes.

Existing DRLM 'List of Product Codes' interface:



DRLM
Device Registration & Listing Module

FURLS HOME
DRLM HOME

Create a New Device Listing

Get Help

- Select Product Code(s)

Shorten your search by using the filter option. Type a word or words describing the device and click Filter. A list of product codes and names will appear below. If you already know the correct product code, type the product code in the box and click Filter. Once you have selected a product code and identified the type(s) of combination product(s) this device is a part of, click Continue.

Enter the Product Code or a word or words describing the device:

> FILTER > CLEAR FILTER

If an exempt product code appears with the selection box grayed out and not selectable, please check to make sure you do not already have a listing for that product code. If you do have an exempt listing for the product code, you must return to the main menu and select Change, Deactivate, or Reactivate Listings, and add any new information to your existing listing.

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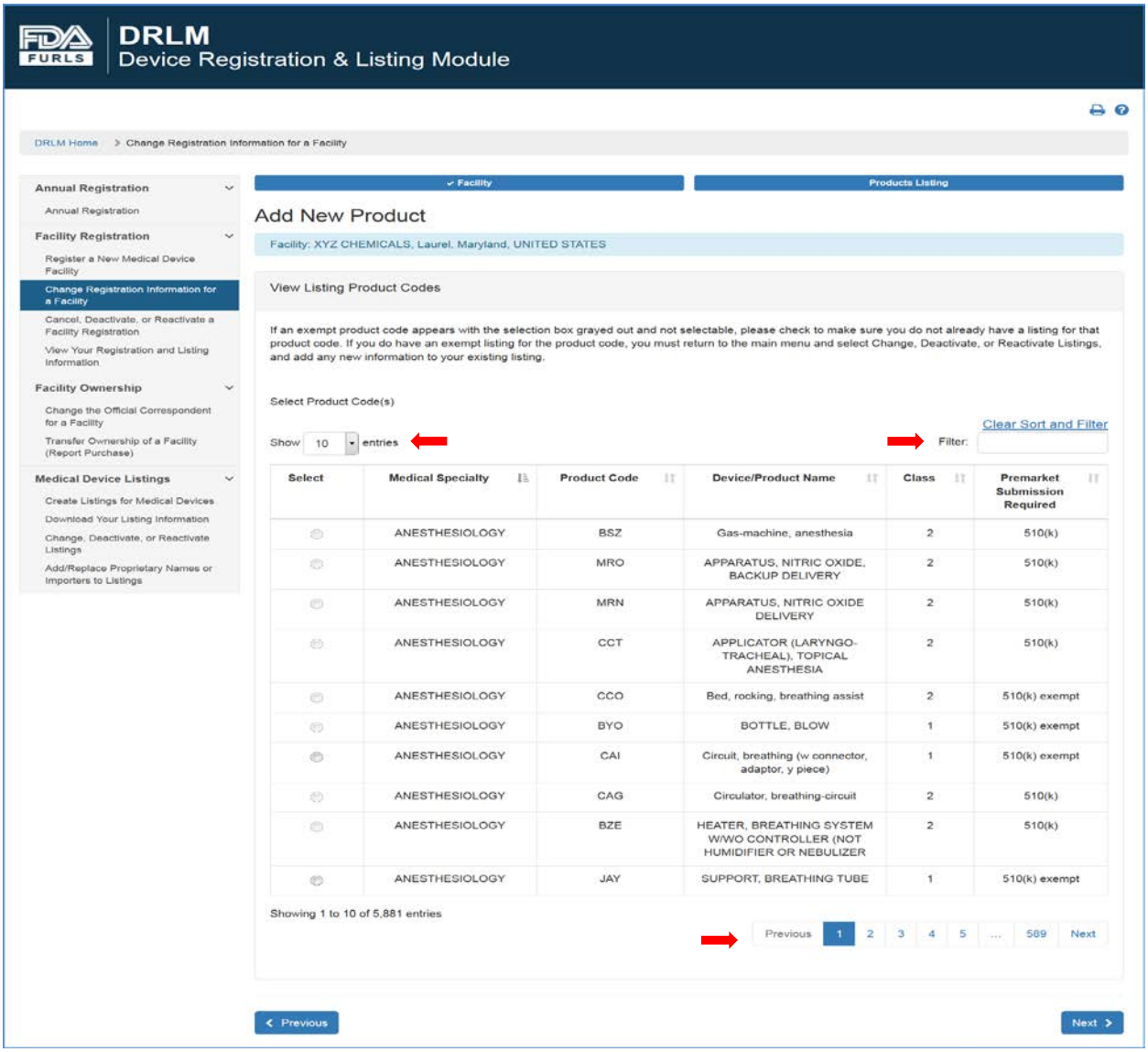
	Medical Specialty	Product Code	Device/Product Name	Class	Premarket Submission Required
	CLINICAL CHEMISTRY	CFG	OIL EMULSION/THYMOLPHTHALEIN (TITRIMETRIC), LIPASE	1	510(k) exempt
	CLINICAL CHEMISTRY	CHI	LIPASE-ESTERASE, ENZYMATIC, PHOTOMETRIC, LIPASE	1	510(k) exempt
	CLINICAL CHEMISTRY	CET	OLIVE OIL EMULSION (TURBIDIMETRIC), LIPASE	1	510(k) exempt
	CLINICAL CHEMISTRY	CFD	SULFOPHOSPHOVANILLIN, COLORIMETRY, TOTAL LIPIDS	1	510(k) exempt
	CLINICAL CHEMISTRY	CFB	CHROMATOGRAPHIC DERIVATIVE, TOTAL LIPIDS	1	510(k) exempt
	CLINICAL CHEMISTRY	JQI	ROTATING DISC, PLASMA VISCOMETRY	1	510(k) exempt
	CLINICAL CHEMISTRY	JHN	TURBIDIMETRIC METHOD, LIPOPROTEINS	1	510(k) exempt
	CLINICAL CHEMISTRY	JHL	MICRODENSITOMETRY METHOD, LIPOPROTEINS	1	510(k) exempt
	CLINICAL CHEMISTRY	MRR	SYSTEM, TEST, LOW DENSITY, LIPOPROTEIN	1	510(k) exempt
	CLINICAL CHEMISTRY	MSJ	APOLIPOPROTEINS	1	510(k) exempt

>> Next

< BACK < CANCEL - RETURN to MAIN MENU > SAVE & EXIT > CONTINUE

Updated DRLM 'List of Product Codes' interface:

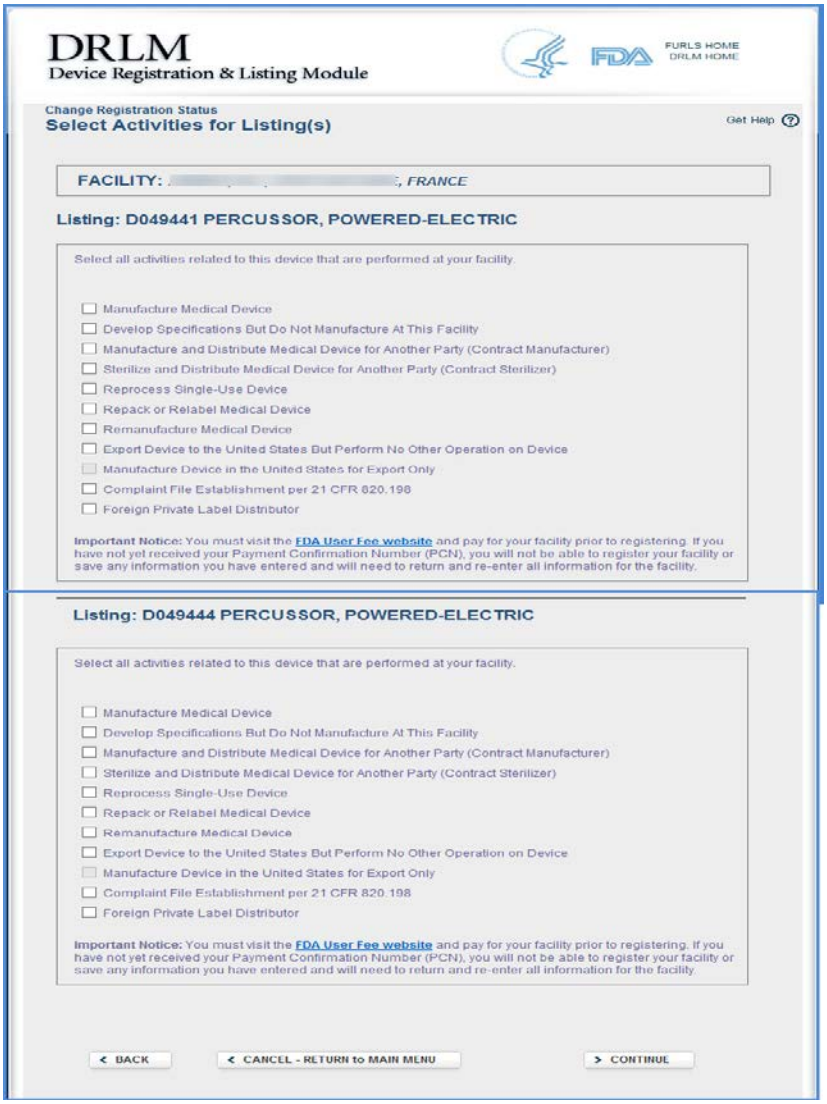


The screen captures displayed should be considered representative of the final changes.

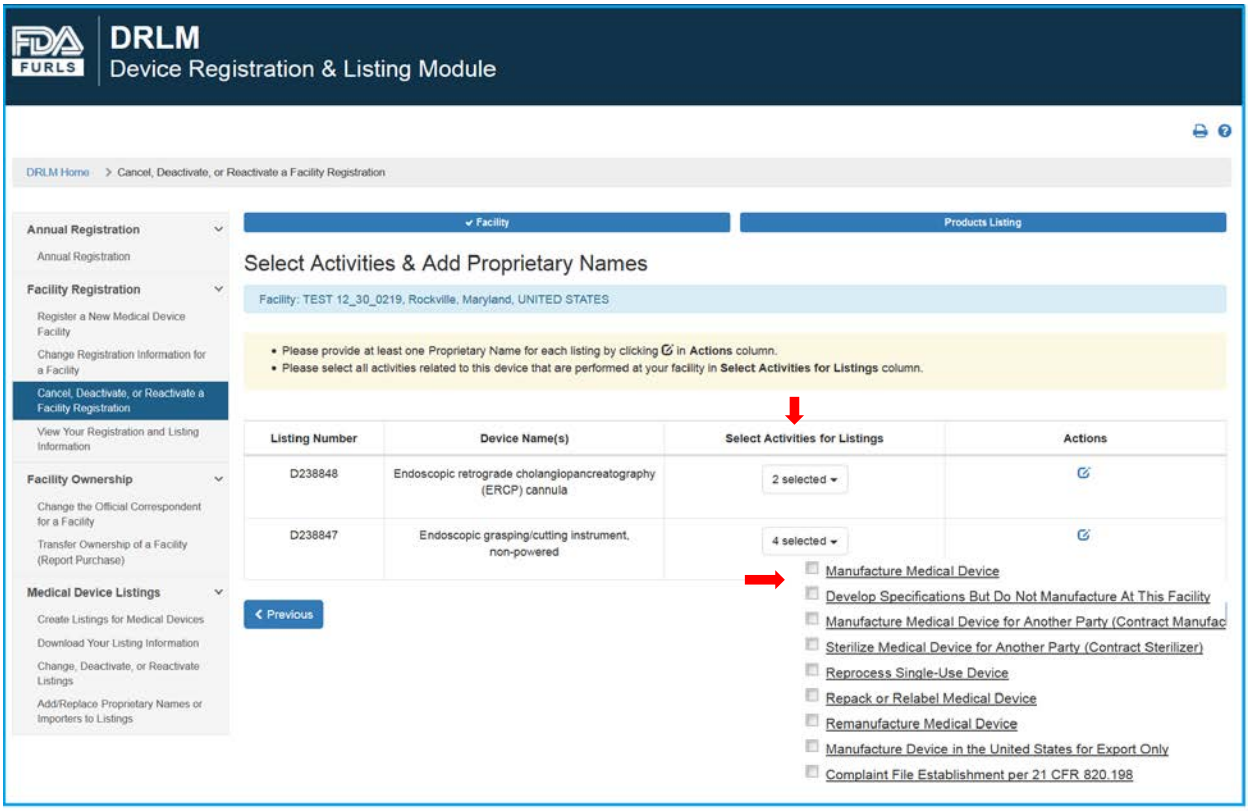
Updated Product Activities Interface

The user interface that allows for a Registration to link an activity related to a product associated with the facility has been revamped. It now features a new user friendly table with 'Select Activities for Listings' column, with a dropdown menu that provides options to users to link activities performed by the product in the facility.

Existing DRLM 'Select Activities for Listing(s)' interface:



Updated DRLM ‘Select Activities for Listing(s)’ interface:



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