FDA resources for reporting on medical devices

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General Information

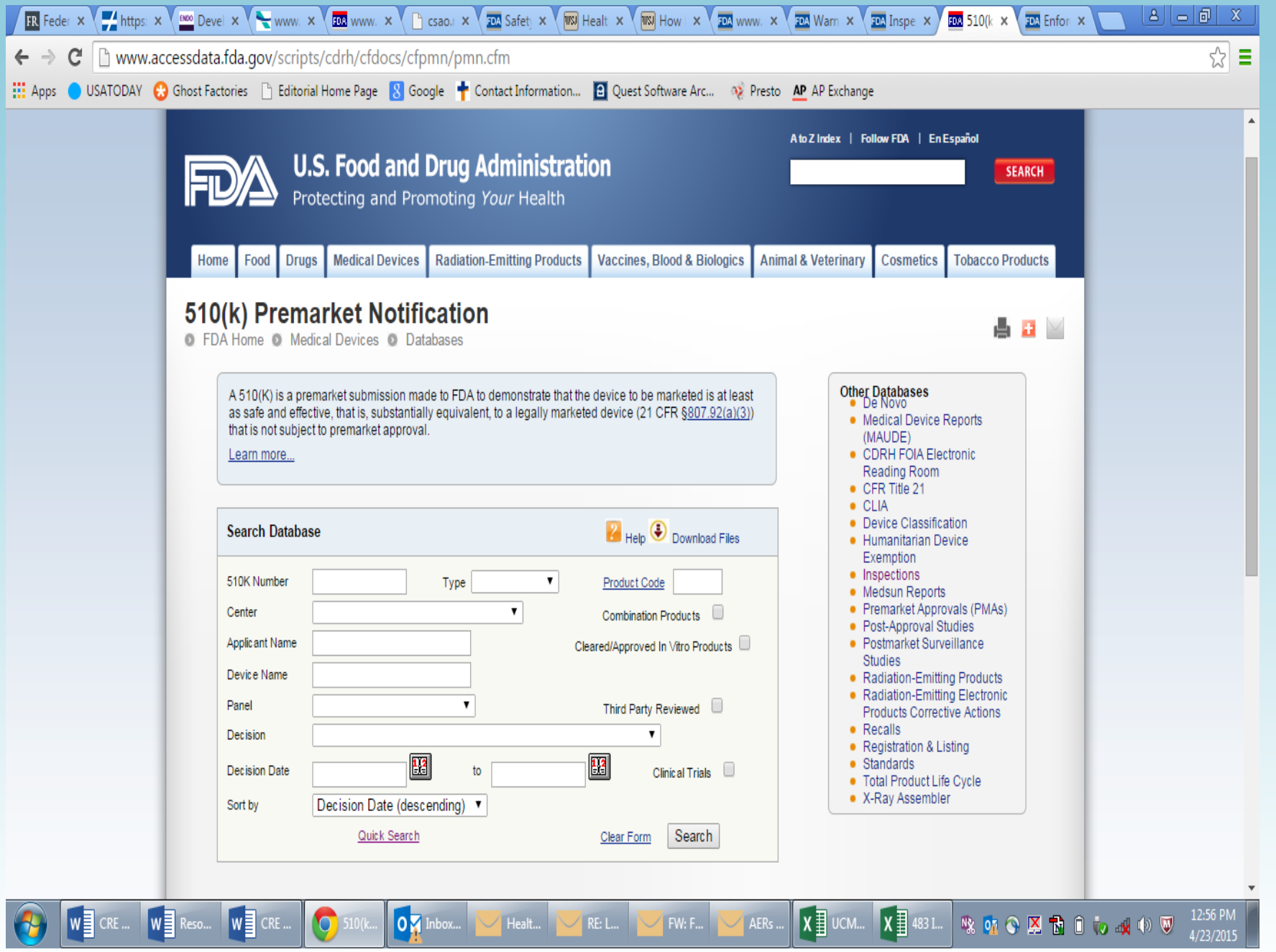
- Medical devices are regulated by the FDA's Center for Devices and Radiologic Health (CDRH). Oversight breaks into two general categories: **pre-market review** and approval, and **post-market surveillance** and control.
- CDRH website, with general background and resources: http://www.fda.gov/MedicalDevices/Safety/default.htm

Pre-market notification and approval:

- Device Classes: There are three regulatory categories for medical devices – Class I, II or III – based on the device's use and the risk it may pose if it doesn't work properly. Class III products are the only ones required to undergo pre-market trials – and the only ones subject to independent risk assessment by the FDA.
  - CRDH explainer on pre-market notification and approval requirements: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm

510k pre-market notification

- The vast majority of medical devices are approved through the 510k clearance process, which requires manufacturers to certifying that they are marketing a device that's substantially similar to technology already on the market. Companies are supposed to validate the device's safety, but the FDA typically does not check that data. If the paperwork is in order, the agency usually grants clearance for the device to go to market.
  - CRDH search page for 510k submissions and clearances: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm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510(k) Premarket Notification
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A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.
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CFR Title 21
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Inspections
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Premarket Approvals (PMAs)
Post-Approval Studies
Postmarket Surveillance Studies
Radiation-Emitting Products
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X-Ray Assembler
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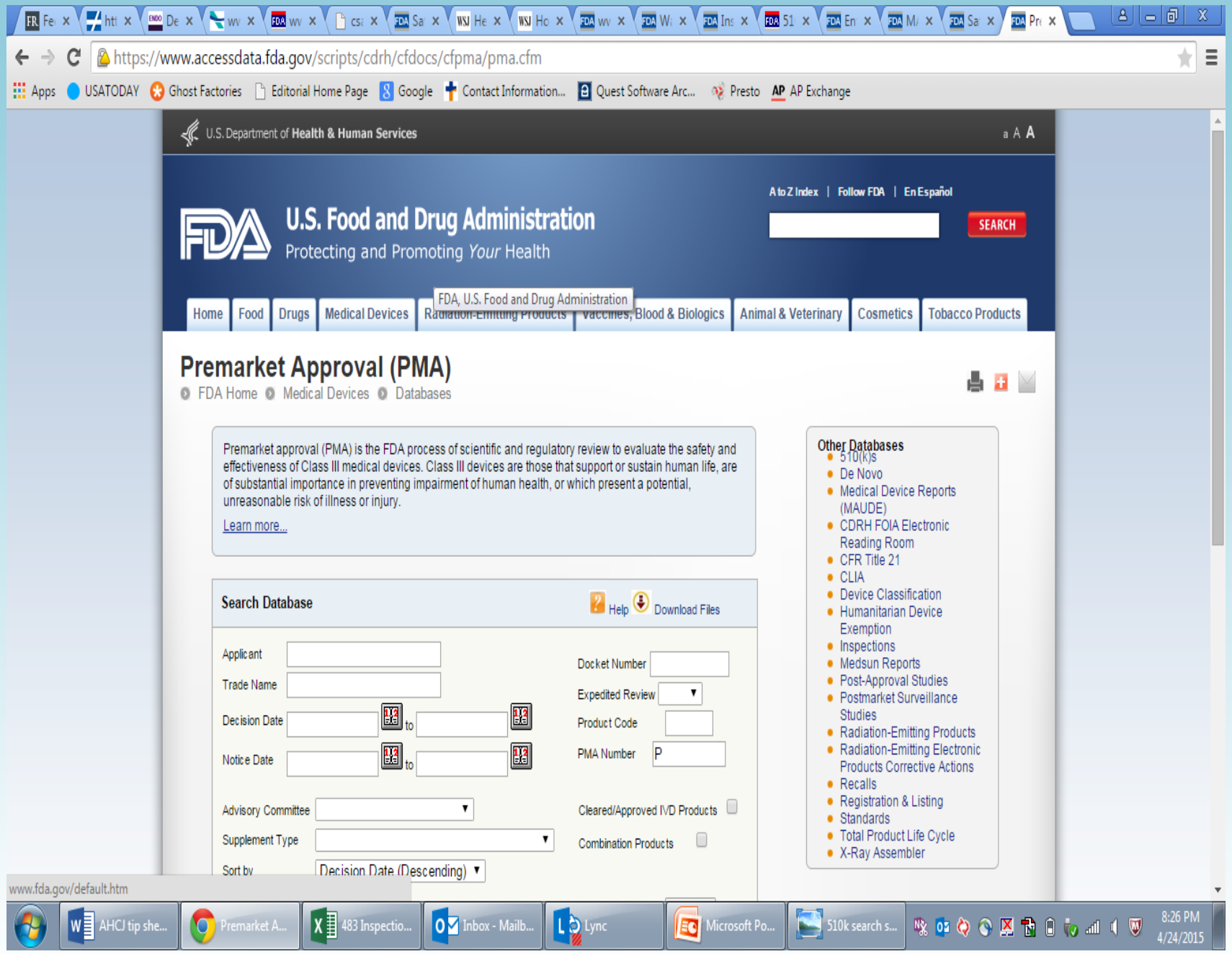
Pre-market approval (PMA)

- This is the more rigorous process for bringing high-risk devices (Class III) to market. Manufacturers submit a PMA application, and the FDA determines whether it contains valid scientific evidence that the device is safe and effective.
  - CRDH search page for PMAs: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm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Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
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CDRH FOIA Electronic Reading Room
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Decision Date
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Post-market oversight, enforcement

- **Adverse Event Reporting:** Manufacturers and health care providers (institutions and individuals) are required to file reports with the FDA when they learn of a potential safety risk with a medical device. The vast majority of this reporting is by manufacturers (the FDA has no enforcement authority over hospitals, doctors and other providers). So the FDA relies heavily on manufacturers to identify safety concerns with medical devices.

- The Manufacturer and User Facility Device Experience (MAUDE) database captures the two types of reports that disclose adverse events linked to medical devices:

    - **Medical Device Reports (MDRs):** Medical device makers are required to file an MDR within 30 days of learning that a product may pose health or safety risks. While health care providers also are supposed to file MDRs under some circumstances, the vast majority come from manufacturers. All MDRs are redacted heavily to shield the identity of the hospital where the reported event occurred.

    - **MedSun Reports:** Medical Product Safety Network (MedSun) reports are generated by a network of 250 or so health care facilities that partner with CDRH to collect information about device problems in hospitals. MedSun reports tend to be more detailed and reliable than MDRs, but they cover a limited number of devices.

MAUDE search page: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

A typical Medical Device Report (MDR)

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=3958702

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MAUDE Adverse Event Report: FUJIFILM OPTICAL CORPORATION, MITO FACTORY FUJINON DUODENOSCOPE

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CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
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FUJIFILM OPTICAL CORPORATION, MITO FACTORY FUJINON DUODENOSCOPE — Back to Search Results

Model Number ED-530XT
Event Date 01/01/2014
Event Type Other
Event Description

On (b)(6) 2014, fujifilm medical systems u. S. A. , inc. (fmsu) was contacted by (b)(6) hospital and advised on fujinon (note: fmsu's endoscopes bear the brand name of "fujinon") duodenoscopes and patients testing positive for cre (carbapenem-resistant enterobacteriaceae).

Manufacturer Narrative

Fujifilm medical systems u. Sa. , inc. (fmsu) immediately initiated an investigation, including a visit to (b)(6), to identify the root cause for the incident. Fmsu personnel were informed that, in response to cre incidents at its sister hospital, (b)(6) had conducted a review of prior medical records for its patient who were positive for cre. At the time of this report, fmsu has been advised that two of three endoscopes ((b)(4)) have allegedly been cultured positive for cre. Three patient who had undergone ercp procedures tested positive for cre and two of three of these patients expressed symptoms consistent with positive cre. The customer is unsure whether the patient transferred cre to the endoscope or vice versa. Non-fujifilm equipment, including a channel cleaning device instead of cleaning brush, is used to manually clean the endoscopes and an aer is used for automated high-level disinfection. A review of fmsu service records for (b)(6) indicated no abnormalities other than general wear and tear repairs attributable to normal usage and handling of the device. Fmsu has requested but has not received any information on any treatment or hospitalizations for these patients, at the time of this initial report. In addition, fmsu has requested that the duodenoscopes that tested positive for cre be returned for a detailed examination. To date, the customer has not returned any duodenoscopes to fmsu. The investigation is still ongoing. Fmsu will submit a supplemental mdr once the investigation is completed.

Search Alerts/Recalls

CRE endoscopes, ... | MAUDE Adverse E... | Lync | Inbox - Mailbox - ... | Naiyana's 14th Bir... | 5:31 PM 4/16/2015

Inspections

- The FDA does occasional surveillance inspections at medical device manufacturing facilities, and deficiencies are documented in Form 483s. The agency has a searchable database of 483 reports, but it's only a list of companies for 483s have been generated (to get the actual report, you must file a request with the FDA):

  http://www.fda.gov/ICECI/Inspections/ucm222557.htm

FDA Enforcement Actions

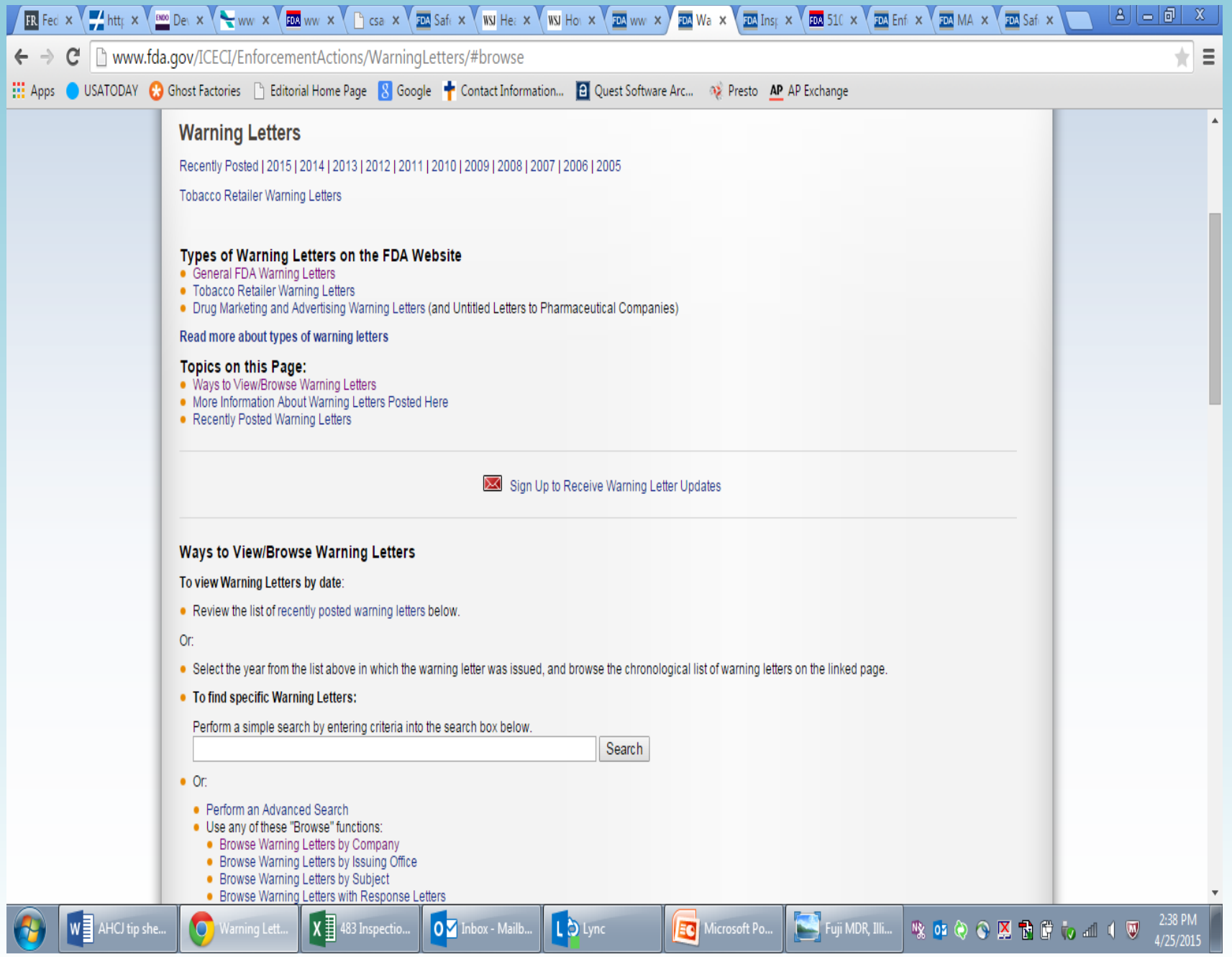
- The FDA has a variety of actions it can take when it learns that a medical device may pose safety risks – warning letters, recalls, safety advisories, etc. There are several databases on the FDA site that are useful for tracking them.

- **Press Releases:** The FDA has a searchable database of press releases listing recalls, market withdrawals and safety alerts, but not all of those actions result in press releases, so the database is not comprehensive: http://www.fda.gov/Safety/Recalls/default.htm

- **Enforcement Reports:** While not all recalls are announced in FDA releases, they all are included in the agency's weekly Enforcement Reports – but not until they are "classified" by hazard level, which can take months. You can search enforcement reports here: http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

- **Warning letters:** When device makers run afoul of regulatory requirements, the agency typically response with a warning letter, which lays out the problem and details the actions required to avoid legal action. These letters all are in searchable database: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/#browse

- **Safety Communications:** If the FDA becomes aware of medical devices that may pose safety risks but don't necessarily carry flaws that require a recall, the agency sometimes issues safety alerts or warnings to health care providers, consumers, or both. You can search those communications by word: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm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