WORLD TRADE ORGANIZATION

G/TBT/N/USA/944

23 December 2014

(14-7419)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** UNITED STATES OF AMERICA **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Food and Drug Administration (FDA), Health and Human Services (HHS) [962] **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above**: Please submit comments to: USA WTO TBT Inquiry Point Email: ncsci@nist.gov
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Prescription drug and biological product labeling; Pharmaceutics (ICS: 11.120)
5.	**Title, number of pages and language(s) of the notified document:** Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products (22 pages, in English)
6.	**Description of content:** The Food and Drug Administration (FDA or the Agency) is proposing to amend its prescription drug and biological product labeling regulations to require electronic distribution of the prescribing information intended for health care professionals, which is currently distributed in paper form on or within the package from which a prescription drug or biological product is dispensed. FDA is also proposing that prescribing information intended for health care professionals will no longer be permitted to be distributed in paper form with the package from which a prescription drug or biological product is dispensed, except as provided by this regulation. We are proposing these actions to help ensure that the most current prescribing information is publicly accessible for the safe and effective use of human prescription drugs.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Prevention of deceptive practices and consumer protection
8.	**Relevant documents:** 79 Federal Register (FR) 75506, 18 December 2014; Title 21 Code of Federal Regulations (CFR) Parts 201, 606 and 610. Will appear in the Federal Register when adopted.
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined
10.	**Final date for comments:** 18 March 2015

11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** http://www.gpo.gov/fdsys/pkg/FR-2014-12-18/html/2014-29522.htm http://www.gpo.gov/fdsys/pkg/FR-2014-12-18/pdf/2014-29522.pdf