The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

This matter concerns advertising, packaging, labeling, and promotional practices related to the sale of Kwikset Corporation's lockset products, including locksets, deadbolts, knobs, and handles. The Commission's complaint charges that respondents misrepresented on packaging and in advertising that certain Kwikset Corporation products are all or virtually all made in the United States. In truth and in fact, these products are actually made with significant foreign content and/or processing.

The proposed consent order contains a provision that is designed to remedy the charges and to prevent the respondents from engaging in similar acts and practices in the future. Part I of the proposed order prohibits Kwikset Corporation from misrepresenting the extent to which any Kwikset lockset is made in the United States. The order defines Kwikset lockset products as any product that is manufactured or sold by Kwikset Corporation that is used to secure doors, including but not limited to locksets, deadbolts, knobs, and handles. The proposed order would allow Kwikset Corporation to represent that such products are made in the United States as long as all, or virtually all, of the components of the products are of U.S. origin, and all, or virtually all, of the labor in manufacturing them is performed in the United States.

The proposed order also prohibits Kwikset Corporation from representing that its products are ''All American Made'' or ''All American Made and Proud of it'' or otherwise entirely made in the United States, unless such products are in fact 100% made in the United States.

Part II of the proposed order requires respondents to maintain materials relied upon in disseminating any representation covered by the order. Part III of the proposed order requires Kwikset Corporation to distribute copies of the order to certain company officials and employees. Part IV of the proposed order requires the respondents to notify the Commission of any change in the corporation that may affect compliance obligations under the order. Part V of the proposed order requires the respondents to file one or more compliance reports. Part VI of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

The purpose of this analysis is to facilitate public comment on the proposed consent order. If is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 01–247 Filed 1–3–01; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1678]

Expansion of Medical Device Industry Initiatives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing some changes in its standard practices for medical device, drug, food, and biologics inspections based on the outcome of the expansion of the medical device industry initiatives pilot program. FDA is discontinuing the practice of post-inspection notification letters for all inspections because the agency now provides inspected establishments with a copy of the establishment inspection report (EIR) when the inspection is deemed closed. FDA has decided to maintain pre-announced inspections and annotations of the inspectional observations (FDA 483) as standard practices for medical device inspections but with respect to inspections of other program areas, to apply these initiatives at the discretion of district management.

DATES: The changes to the medical device and expansion programs are effective January 1, 2001, with the publication of FDA's 2001 edition of the Investigations Operations Manual (IOM). Written comments may be submitted at any time in accordance with FDA's good guidance practices.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise D. Dion, Office of Regulatory Affairs (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5645, FAX 301–443–6919.

SUPPLEMENTARY INFORMATION: During the FDA/medical device industry grassroots forums in 1995, several issues were discussed concerning FDA's interaction with the medical device industry. A decision was made to consider action on three of the inspectional issues discussed. These included instituting: (1) Pre-announced inspections, (2) listing promised or completed corrective actions on FDA 483 items, and (3) post-inspection notification to establishments regarding their compliance status.

In fiscal year (FY) 1996, FDA initiated a pilot program for the medical device industry, implementing these three changes. The pilot program took place during the 1996 calendar year and was limited to inspections of medical device manufacturers that did not manufacture products that crossed other program areas such as drugs or biologics. Pre-announced inspections were offered to those medical device firms that met the criteria for inclusion in the pilot program. The criteria included nonviolative current good manufacturing practices inspectional histories and a history that records and individuals were available at earlier pre-announced inspections. FDA 483 annotations and the post-inspection notification were done for all medical device inspections whether or not the inspection was pre-announced.

Based on industry input, FDA initiated another year-long pilot program in January 1999, to provide similar coverage for program areas including drugs (both human and animal) and biologics. Food inspections were limited to FDA 483 annotations and post-inspection notification. In FY 2000, FDA considered the impact of the second pilot's effects on field operations. The intent of the medical device pilot program was to optimize resource utilization, enhance FDA/industry communications, and provide firms prompt closure for nonviolative inspections and for corrected inspection observations. However, FDA determined that the additional burdens placed on field staff by the expansion into other program areas failed to capitalize resources and reduced overall field inspectional productivity.

FDA believes that the new inspection method for medical device firms (the quality system inspection technique) implemented in October 1999 provides

a clear direction in the inspection of these establishments, and provides logical stopping points, thus making the time it takes to complete an inspection more predictable. FDA concludes that pre-announcement of medical device inspections will remain standard procedure based on the defined criteria. For other establishments, pre-announcement of inspections remains voluntary at the discretion of the local FDA office. FDA will continue generally not to pre-announce inspections of food, blood bank, and plasmapheresis centers, but this, too, will be left to the district's discretion.

FDA investigators traditionally have discussed their observations with appropriate management at the establishment at the conclusion of the inspection. These discussions are reported in the Establishment Inspection Report. FDA will continue that practice, and will rely on the discretion of the investigator/team to determine whether to annotate the FDA 483. Since the medical device industry specifically asked FDA for annotations of the FDA 483, and since FDA has not found this practice to adversely affect the inspection process for medical devices, annotations will remain standard procedure for medical device inspections only.

In April 1997, FDA implemented a Field Management Directive (FMD 145) that requires FDA field offices to provide a copy of the EIR to the inspected establishment once the inspection is deemed closed. The copy of the EIR is provided along with a letter referred to as the ''FMD 145 letter.'' FDA has found that the issuance of both a post-inspection notification (PIN) letter and a FMD 145 letter is redundant. Because of this redundancy and the burden this puts on the field, the PIN letters will be discontinued in all program areas. FMD 145 will remain in place and these letters will continue to be issued. Establishments will receive a copy of their EIR when the inspection is deemed closed based on 21 CFR 20.64(d).

The 2001 IOM will be posted to FDA's website at www.fda.gov/ora under Inspection References/Investigations Operations Manual. The IOM sections that apply are: 510, 512.3, 516, 529 and 551.1. FMD 145 is posted to FDA's website at www.fda.gov/ora under Inspection References/Field Management Directives.

Dated: December 27, 2000.

John Marzilli,

Deputy Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–141 Filed 1–3–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1681]

Draft Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.'' This draft guidance updates a notice of availability entitled ''Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use'' published in the **Federal Register** on June 29, 1982, concerning the prophylactic use of potassium iodide (KI) in the event of release of radioactive isotopes of iodine. In the draft guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified condition for use, and thus to obviate the risk of thyroid cancer in the event of a radiation emergency.

DATES: February 5, 2001.

ADDRESSES: Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Executive Operations (HFD–06), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.''

The Federal Emergency Management Agency has established roles and responsibilities for Federal agencies in assisting State and local governments in their radiological emergency planning and preparedness activities. The Federal agencies, including the Department of Health and Human Services (DHHS), are expected to accomplish these roles and responsibilities as part of the Federal Radiological Preparedness Coordinating Committee. Among other responsibilities, the DHHS is to provide guidance on the use of radioprotective substances to reduce radiation doses to specific organs from the release into the environment of large quantities of radioactivity. FDA is specifically charged with providing guidance on the prophylactic use of KI in the event of release of radioactive isotopes of iodine.

FDA is announcing the availability of a draft guidance that updates the notice of availability, ''Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use,'' published in the **Federal Register** of June 29, 1982 (47 FR 28158). In this draft guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified conditions of use, and thus to lessen the risk of thyroid cancer in the event of a radiation emergency. In this draft guidance, FDA proposes lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended. FDA's revised recommendations are in general accordance with those of the World Health Organization (WHO), as expressed in its ''Guidelines for Iodine Phrophylaxis Following Nuclear Accidents'' (1999), though they differ from those of the WHO in two areas.

First, for the sake of logistical simplicity, FDA recommends the 65-milligram (mg) dose of KI for all school-age children while allowing for the full adult dose of 130 mg in adolescents approaching adult size. WHO recommends 130 mg KI for adults and adolescents (over 12 years of age). Second, FDA recommends that KI prophylaxis in those under age 19 and in pregnant or lactating women be triggered at a predicted thyroid radioiodine exposure of 5 centiGray (cGy), while WHO establishes 1 cGy as the threshold for intervention. FDA has concluded from the Chernobyl data that the most reliable evidence demonstrates