

Stang, Annette

From: Milligan, Patricia
Sent: Wednesday, November 20, 2013 9:40 AM
To: Stang, Annette
Subject: FW: KI Replenishment for Massachusetts

From: Anderson, Beverly (DPH) [mailto:beverly.anderson@state.ma.us]
Sent: Wednesday, November 20, 2013 9:37 AM
To: Milligan, Patricia
Cc: Iannaccone, Mario (DPH); Savastano, Gus (DPH)
Subject: RE: KI Replenishment for Massachusetts

Trish—Thanks so much for your response. We understand that this is a difficult process.

Beverly

Beverly E. Anderson, MPH, RS
Interim Director, Radiation Control Program
Bureau of Environmental Health
Massachusetts Department of Public Health
250 Washington Street, Boston, MA 02108

Tel: (617) 624-5757
(617) 242-3035

From: Milligan, Patricia [mailto:Patricia.Milligan@nrc.gov]
Sent: Tuesday, November 19, 2013 4:44 PM
To: Giarrusso, John (CDA); Savastano, Agostino (DPH); Anderson, Beverly (DPH); Iannaccone, Mario (DPH)
Cc: Stang, Annette
Subject: RE: KI Replenishment for Massachusetts

Hi,

We are working to ensure that your KI delivery arrives as soon as we can get it to you. As you know, the federal government has faced budget challenges this year. The shutdown added additional challenges and given that the shutdown occurred at the very beginning of the fiscal year, we had yet more challenges. But we are on track to purchase KI and the optimist in me would like to tell you that you will have it by the end of Feb. The realist in me urges appropriate caution and likely the latest it would be received would be in the March-April 2014 timeframe.

KI is a very stable substance. It is the “active” ingredient in iodized salt. The tablets will still be good for use after the expiration date. I’ve attached the FDA guidelines on shelf life extension and I have excerpted the following from that document- see page 4. (I highlighted the key points.) We are working with FDA and FEMA on this. Thank you so much for your understanding and patience. I apologize for any and all problems this may be causing you. Annette or I will keep you up to date on the process over the next few months including when you can expect your delivery. If you haven’t done so, please send Annette the up-to-date “ship to “ information including a telephone number and contact person.

Don’t hesitate to email or call if you have additional questions or concerns.

Happy Thanksgiving.

“A. Observations About KI Tablet Stability Based on Historical Data

Potassium Iodide Tablets, USP, is a compendial drug product that is manufactured to meet the recommended tests and specifications listed in the USP monograph. Assay and dissolution are the two specifications with potential relevance to stability, assuming identification and content uniformity testing were performed at release.¹¹ **Stability studies over many years have confirmed that none of the components of KI tablets, including the active ingredient, has any significant potential for chemical degradation or interaction with other components or with components of the container closure system when stored according to labeled directions.**

To date, the only observed changes during stability testing have been the failure of some batches of KI tablets to meet the USP S₁ dissolution specification, Q=75 percent in 15 minutes. **Some tablets tested required slightly longer than the specified time to achieve dissolution, but even in the case of a failure of this sort, the product would remain usable.** In such cases, instructions can be provided to crush the tablets and mix them with a juice or other liquid prior to administration as suggested for emergency pediatric dosing (see Home Preparation Procedures document cited above). In any long-term stability evaluation, appearance should be monitored as a matter of course. In the specific case of KI tablets, a yellowish discoloration would be indicative of stability problems. **Since pure KI is known to be very stable (as long as it is protected from moist air),¹² ongoing evaluation and testing of each batch is probably unnecessary as long as the market package remains intact and continues to be stored under controlled conditions as described in the labeling.”**

Trish

Patricia A. Milligan, CHP, RPh
Senior Level Advisor for Preparedness and Response
Office of Nuclear Security and Incident Response
US Nuclear Regulatory Commission
Three White Flint North
MS 3WFN-09D-14
11601 Landsdown St.
North Bethesda, MD 20852
301-287-3739

From: Savastano, Gus (DPH) [<mailto:gus.savastano@state.ma.us>]
Sent: Tuesday, November 19, 2013 8:50 AM
To: Stang, Annette
Cc: Anderson, Beverly (DPH); Giarrusso, John (CDA); Iannaccone, Mario (DPH)
Subject: RE: KI Replenishment for Massachusetts

Annette,

As the new supply of KI will be arriving later than the current stock date of 2-14, will the KI manufacturer be providing a letter to extent the expiration till we receive the new shipment?

We understand that the replenishment KI may not arrive till the second quarter of 2014.

Best regards,

Gus Savastano

From: Stang, Annette [<mailto:Annette.Stang@nrc.gov>]

Sent: Tuesday, July 16, 2013 4:49 PM

To: Giarrusso, John (CDA)

Cc: Savastano, Agostino (DPH); McNamara, Nancy; Suarez, Kenyi (CDA); Cederberg, Katharine (CDA); Cleary, Tom (CDA); Milligan, Patricia

Subject: RE: KI Replenishment for Massachusetts

Mr. Giarrusso,

At this time, it is uncertain if NRC will be able to support any requests for increase in tablet quantities. We are currently in the process of obtaining a contract for KI and will let you know if we can fulfill the request for additional tablets in the near future. The additional tablets you are requesting would be approximately 53,200 (65 mg). This would put the total of tablets for MA at 1,153,200.

Please let me know if you have any questions.

Annette Stang

Annette Stang (Note: New contact info)

*U.S. Nuclear Regulatory Commission
Office of Nuclear Security & Incident Response
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11601 Landsdown Street
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301-287-3780*

From: Giarrusso, John (CDA) [<mailto:john.giarrusso@state.ma.us>]

Sent: Tuesday, July 16, 2013 1:49 PM

To: Stang, Annette

Cc: Savastano, Gus (DPH); McNamara, Nancy; Suarez, Kenyi (CDA); Cederberg, Katharine (CDA); Cleary, Tom (CDA)

Subject: KI Replenishment for Massachusetts

Annette

I work closely with Gus on the Nuclear Program for Massachusetts. My responsibility is the emergency preparedness for the 3 nuclear plants that are in or border our Commonwealth. Concerning KI, will the NRC be replenishing the KI we have in place for emergency workers to support the emergency response to the plants?

We have 1900 packets (14 pills per packet) of 130mg each. Reading the emails below it looks like that NRC will not be supplying 130mg and only 65mg. If that is the case we would need 3800 packets of the 65mg.

My contact information is below and please give me a call with any questions

Thanks

john

John Giarrusso, Jr.

Planning, Preparedness, & Nuclear Section Chief

MEMA

(W) 508-820-2040

(C) 603-817-0560

From: Savastano, Agostino (DPH)

Sent: Tuesday, July 16, 2013 1:37 PM

To: Giarrusso, John (CDA)
Subject: FW: KI Replenishment for Massachusetts

KI Contact

From: Stang, Annette [<mailto:Annette.Stang@nrc.gov>]
Sent: Monday, May 20, 2013 11:30 AM
To: Savastano, Agostino (DPH)
Cc: Dell'Olio, Lou (DPH); Anderson, Beverly (DPH); Iannaccone, Mario (DPH); Milligan, Patricia
Subject: RE: KI Replenishment for Massachusetts

Good Morning Gus,

Thank you for your e-mail and delivery address. We will be in contact with you a couple of weeks prior to the delivery date. Please let me know if you have any additional questions/concerns.

Thank you,
Annette Stang

Annette M. Stang, EP Analyst
Nuclear Regulatory Commission
DPR/EP/IRIB
Two White Flint North (T-3B46M)
11545 Rockville Pike
Rockville, Maryland 20855
301-415-2918
Annette.Stang@nrc.gov

From: Savastano, Gus (DPH) [<mailto:gus.savastano@state.ma.us>]
Sent: Monday, May 20, 2013 11:22 AM
To: Stang, Annette
Cc: Dell'Olio, Lou (DPH); Anderson, Beverly (DPH); Iannaccone, Mario (DPH)
Subject: RE: KI Replenishment for Massachusetts

Annette,

This email is to notify you that Massachusetts would like to participate in the KI replenishment program for the EPZ communities.

The number of KI tabs that you specify in your email below dated March 8, 2013 is adequate for our needs. We understand that the NRC will only replenish the amount that was shipped to us the last go around. We also understand that we will only be receiving 65 mg instead of 130 mg (2 for adult and 1 for child) in the total of 1,100,000 (65 mg) tablets. The address for KI delivery would be the following:

Louis Dell'Olio, Director
Commonwealth of Massachusetts
Office of Pharmacy Services
365 East Street
Tewksbury, Massachusetts 01876
(978) 858-2100

The contact for the Massachusetts Department of Public Health, Radiation Control Program is Beverly Anderson (617) 242-3035 x 2001. We will contact you with any special delivery requests.

Best regards,

Gus

Gus Savastano, Emergency Planner
Massachusetts Department of Public Health
Bureau of Environmental Health
Radiation Control Program
Schrafft Center, Suite 1M2A
529 Main Street, Charlestown, MA 02129
617/242-3035 x2028
617/242-3457 Fax
617/697-7214 Cell

From: Stang, Annette [<mailto:Annette.Stang@nrc.gov>]
Sent: Tuesday, April 30, 2013 2:54 PM
To: Savastano, Agostino (DPH)
Subject: RE: KI Replenishment for Massachusetts

Hi Gus,

I just left a message on your voicemail. Please give me a call at your convenience.

Thank you,
Annette Stang

Annette M. Stang, EP Analyst
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Annette.Stang@nrc.gov

From: Savastano, Gus (DPH) [<mailto:gus.savastano@state.ma.us>]
Sent: Tuesday, April 23, 2013 12:59 PM
To: Stang, Annette
Subject: RE: KI Replenishment for Massachusetts

Annette,

Can you please contact me regarding KI for Massachusetts?

Thanks,

Gus

Gus Savastano, Emergency Planner
Massachusetts Department of Public Health
Bureau of Environmental Health
Radiation Control Program
Schrafft Center, Suite 1M2A
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617/242-3035 x2028
617/242-3457 Fax
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From: Stang, Annette [<mailto:Annette.Stang@nrc.gov>]
Sent: Friday, March 08, 2013 4:14 PM
To: Anderson, Beverly (DPH); Savastano, Agostino (DPH)
Cc: Milligan, Patricia
Subject: KI Replenishment for Massachusetts

Hello,

The NRC is preparing to replenish expiring stockpiles of KI tablets. According to our records your State has 550,000 (130mg) tablets with lot numbers PO3-4, expiring in February 2014. We are no longer supplying (130mg) tablets and will replace stockpiles with (65mg) tablets (2 per adult and 1 per child). We will replace your (130mg) tablets with 1,100,000 (65 mg) tablets. The NRC will replace the expiring stockpiles during fiscal year 2014. If your State wishes to participate in the NRC KI tablet replenishment, please respond with the delivery address, point of contact (including phone number) and any special delivery requests you have no later than May 31, 2013. Please note these tablets will not be shipped until 2014 to ensure timely replacement of your States expiring KI stockpiles. We will notify you prior to shipment of the tablets to enable you to make any preparations necessary for receipt.

Thank you so much for your prompt attention to this matter. I look forward to your response. Please let me know if you have any questions.

Thank you,
Annette Stang

Annette M. Stang, EP Analyst
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Guidance for Federal Agencies and State and Local Governments

Potassium Iodide Tablets Shelf Life Extension

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2004
Procedural

Guidance for Federal Agencies and State and Local Governments

Potassium Iodide Tablets Shelf Life Extension

Additional copies are available from:

Office of Training and Communication
Division of Drug Information, HFD-240
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857 (Tel) 301-827-4573
<http://www.fda.gov/cder/guidance/index.htm>

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2004
Procedural

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Contains Nonbinding Recommendations

Guidance for Federal Agencies and State and Local Governments¹

Potassium Iodide Tablets Shelf Life Extension

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if that approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This document is intended to provide guidance to Federal agencies and to state and local governments on testing to extend the shelf life of stockpiled potassium iodide (KI) tablets. The Agency has developed this document in response to several state inquiries on this topic. This guidance discusses FDA recommendations on testing for such shelf life extensions, the qualifications of laboratories suitable to conduct the tests, and issues regarding notification of holders of stockpiled KI tablets as well as end users² about changes to batch shelf life once testing has been successfully conducted.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Regulatory Framework

¹ This guidance has been prepared by the Office of Pharmaceutical Science (OPS) in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

² For purposes of this guidance, end users are consumers who have purchased KI, or intermediate holders of KI, such as fire departments, health departments, hospitals, or other entities who store KI for use in emergencies.

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FDA has approved two new drug applications (NDAs) for Potassium Iodide Tablets, USP.³ Both applications⁴ were approved prior to 1985 and currently provide for marketing of 130-mg KI tablets over the counter (OTC) (i.e., without a prescription). Potassium iodide tablets manufactured by one or both holders of these NDAs have been stockpiled under controlled conditions for use in a radiation emergency.

An abbreviated new drug application (ANDA)⁵ for Potassium Iodide Tablets, USP (65 mg), was approved on September 10, 2002.⁶

B. HHS Role in Radiological Planning and Preparedness Activities

Under 44 CFR 351, the Federal Emergency Management Agency (FEMA) 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 (HHS), are to carry out these roles and responsibilities as members of the Federal Radiological Preparedness Coordinating Committee (FRPCC). Under § 351.23(f), HHS is directed to provide guidance to state and local governments on the use of radioprotective substances and the prophylactic use of drugs (e.g., KI tablets) to reduce the radiation dose to specific organs, including dosage and projected radiation exposures at which such drugs should be used. As a part of HHS, FDA has been providing relevant guidance to other agencies and the public on KI.

C. FDA Guidance on Safe and Effective Use of KI as a Radioprotective Agent

In November 2001, FDA provided guidance on the safe and effective use of KI tablets as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment. The guidance Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies updated FDA's 1982 recommendations for the use of KI tablets to reduce the risk of thyroid cancer in radiation emergencies involving the release of radioactive iodine. The recommendations in that guidance addressed KI dosage and the projected radiation exposure at which the drug should be used. In April 2002, FDA issued another document, Frequently Asked Questions on Potassium Iodide (KI). Additional information was provided for emergency pediatric dosing in Home Preparation Procedure for Emergency Administration of Potassium Iodide Tablets to Infants and Small Children (Home Procedures document), updated on July 3, 2002.⁷

³ United States Pharmacopeia.

⁴ NDAs 18-307 and 18-664.

⁵ Application ANDA 76-350.

⁶ For an up-to-date listing of all approved KI products, consult the online version of FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (Electronic Orange Book) at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

⁷ The guidance and home preparation information can be found at <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm080542.pdf>, <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm072265.htm>, and <http://www.fda.gov/kiprepare>, respectively.

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D. Shelf Life Extension of KI Tablets

A number of state and local governments maintain stockpiles of KI tablets for use in the event of a radiation emergency involving the release of radioactive iodine. Several states have asked FDA what would be necessary to provide confidence that stockpiled KI tablets have retained their original quality (i.e., purity and potency) after passing the expiration date.

Previously, two approaches have been used to extend the shelf life of expired drug products: (1) the ordinary approach taken by drug manufacturers, and (2) the Department of Defense (DOD) Sponsored Shelf Life Extension Program.

1. Ordinary Shelf Life Extension

In the preferred method of shelf life extension for drug manufacturers, the manufacturer of an approved drug product may propose an extension of the expiration dating period for that product based on acceptable data from full, long-term stability studies on at least three production batches in accordance with a protocol approved in the application. The data can be reported and FDA can be notified of the extension of the expiration dating period in an annual report submitted to the NDA or ANDA if, after obtaining and analyzing the data in accordance with the protocol, the criteria set forth in the approved stability protocol are met.⁸

2. DOD-Sponsored Shelf Life Extension Program

Certain drug products have been qualified for shelf life extension through the Shelf Life Extension Program (SLEP), which is sponsored by the DOD and performed by FDA. The SLEP is sponsored by the DOD because of the substantial savings to the government from extending the shelf life of certain antibiotics and other drug products of strategic importance that are stored in Federal stockpiles in large quantities under controlled conditions.

It is unlikely that any manufacturer of KI tablets would be willing to conduct testing of all of the lots of KI tablets that have already been distributed, and it would be infeasible for FDA to include KI tablets in a DOD-sponsored program. Because several states have inquired about possibly testing stockpiled KI for shelf life extension, the Agency is providing this guidance on testing for such shelf life extensions of KI that is being stockpiled under controlled conditions. The Agency is also providing guidance on how to identify laboratories suitable to conduct the tests, how to notify holders of stockpiled KI tablets and end users about changes in shelf life,⁹ and how to distinguish stockpiled batches with different shelf lives.

⁸ In June 1998, the Agency issued a draft guidance on stability testing, *Stability Testing of Drug Substances and Drug Products*. Once finalized, this guidance will represent the Agency's current thinking on this topic.

⁹ The shelf life extension testing described in this guidance can provide confidence only that KI that has been stored in accordance with the conditions described in the labeling will retain its potency and quality for an extended period of time.

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III. DISCUSSION

Studies conducted during the SLEP program on a variety of drug products have shown that shelf lives of most drug products can be extended well beyond their expiration dates, but the additional stability period for a given drug can be highly variable. It was concluded that, due to lot-to-lot variability, the stability and quality of drug products with extended expiration dates could only be assured by continual testing and systematic evaluation of each lot.¹⁰

A. Observations About KI Tablet Stability Based on Historical Data

Potassium Iodide Tablets, USP, is a compendial drug product that is manufactured to meet the recommended tests and specifications listed in the USP monograph. Assay and dissolution are the two specifications with potential relevance to stability, assuming identification and content uniformity testing were performed at release.¹¹ Stability studies over many years have confirmed that none of the components of KI tablets, including the active ingredient, has any significant potential for chemical degradation or interaction with other components or with components of the container closure system when stored according to labeled directions.

To date, the only observed changes during stability testing have been the failure of some batches of KI tablets to meet the USP S₁ dissolution specification, Q=75 percent in 15 minutes. Some tablets tested required slightly longer than the specified time to achieve dissolution, but even in the case of a failure of this sort, the product would remain usable. In such cases, instructions can be provided to crush the tablets and mix them with a juice or other liquid prior to administration as suggested for emergency pediatric dosing (see Home Preparation Procedures document cited above). In any long-term stability evaluation, appearance should be monitored as a matter of course. In the specific case of KI tablets, a yellowish discoloration would be indicative of stability problems. Since pure KI is known to be very stable (as long as it is protected from moist air),¹² ongoing evaluation and testing of each batch is probably unnecessary as long as the market package remains intact and continues to be stored under controlled conditions as described in the labeling.

B. Recommended Protocol for Shelf Life Extension of KI Tablets

An example of a protocol for shelf life extension of KI tablets from a given manufacturer (manufacturer A) of stockpiled KI tablets is illustrated in the table later in this section.

¹⁰ "Stability Profiles of Drug Products Extended Beyond Labeled Expiration Dates," AAPS Poster Session, November 2001, Center for Drug Evaluation and Research, Office of Pharmaceutical Sciences, Division of Product Quality Research.

¹¹ The quality control division of the manufacturer performs identification and content uniformity testing before the product can be released for sale.

¹² "Slightly deliquescent in moist air; on long exposure to air becomes yellow due to liberation of iodine, and small quantities of iodate may be formed; light and moisture accelerate the decomposition," The Merck Index, 12th edition, 7809, Potassium Iodide.

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We recommend that samples of three batches of KI tablets from each manufacturer be selected and stored under controlled conditions of temperature and humidity and that the samples be tested periodically for compliance with the USP assay and dissolution specifications. Each sample should consist of at least 25 tablets per test, but it would be prudent to select larger samples so that sequential testing and extensions can be performed indefinitely. Accelerated stability testing storage conditions are 40°C/75% relative humidity (R.H.). These conditions stress the product and are thought to be conservatively predictive of future stability for a period of time under room temperature conditions. Accelerated data are commonly used to establish initial expiration dates for pharmaceuticals. The expiration dates are confirmed with real time stability data. For KI tablets, results of these tests could support shelf life extensions as follows:

- If the testing results are acceptable after 3 months of storage under accelerated storage conditions, all batches of KI tablets from that manufacturer can be considered to be tentatively qualified for an additional 2 years.
- We recommend that additional samples of the three batches, stored at room temperature in a warehouse or other facility, be tested at the end of 2 years from the date of initial sampling to confirm the shelf life extension tentatively qualified by the accelerated studies.
- After this confirmation, additional shelf life extensions in increments of 2 years can be qualified in the same fashion (i.e., 3 months storage at accelerated conditions followed by confirmatory data from samples stored at room temperature for 2 years).

We recommend that adequate records of the testing be kept even when a batch fails stability testing.

As already mentioned, in any long-term stability evaluation, we recommend that appearance be monitored. Discoloration of the tablets would provide an early indication of stability problems.

Table: Example of a Protocol for Shelf Life Extension

Batch Identification	Conditions	Start date	Finish date	Tests/Specifications* per USP: Assay: 60.1-69.9 mg Diss.: 75% in 60 min. Appearance			Stations Monitored	Shelf life	Expiry
Manufacturer A	90 days accelerated.	10/1/02	12/31/02	√	√	√	0, 1, 2, 3 months	5 years (tentative)	10/04 (tentative)
"	24 months long term confirmatory	10/02	ongoing	√	√	√	0, 3, 6, 9, 12, 18, 24 months	5 years (confirmed)	10/04 (confirmed)
"	90 days accelerated	10/1/04	12/31/04	√	√	√	0, 1, 2, 3 months	7 years (tentative)	10/06 (tentative)
"	24 months long term confirmatory	10/02	ongoing	√	√	√	0, 3, 6, 9, 12, 18, 24 months	7 years (confirmed)	10/06 (confirmed)

***Test**

Potassium Iodide (USP method – titration)
Dissolution
Appearance (visual) (Not USP)

USP Specification

60.1– 69.9 mg (92.5% - 107.5%) (65 mg tablet)
NLT 75% (Q) of labeled amount in 15 minutes
No appreciable discoloration

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C. Identifying a Suitable Laboratory

If the decision is made to contract to have shelf life testing performed, we recommend that a suitable laboratory be identified. The testing suggested in this guidance is uncomplicated, and most laboratories should be capable of performing the tests. General laboratory GMPs are discussed in detail in Guide to Inspections of Dosage Form Drug Manufacturer's CGMPs.¹³ The recommended assay test is a titration. Dissolution testing and the requisite apparatus are adequately described in the USP. Because these are compendial tests, the validation of methodology is straightforward (i.e., typical parameters are listed in USP <1225>). Potassium iodide is a very soluble drug substance and will be dissolved in the specified medium upon tablet disintegration, confirmed by measurement of the UV (ultraviolet) absorbance at the specified wavelength using a UV spectrophotometer.

D. Identification of Batches Qualified for Extension and Notification of Expired Batches

Once KI tablets from a given manufacturer have been qualified for shelf life extension by the program described above, we recommend that some provision be made to notify holders of stockpiled KI and end users as to which drug product has been qualified and what the new expiration date should be. The identification and notification procedures should be amenable to additional extensions. Potassium iodide tablets that are centrally stored can be shrink wrapped and marked with the qualified shelf life extension dates to distinguish them from other KI tablets that have different expiry dates. Each individual container need not be relabeled. End users can be notified of the extension of the expiration date using the batch identification number on each bottle.

Due to the inherent stability of KI tablets, stockpiled or distributed batches will probably not need to be replaced frequently. As noted previously, even if a batch fails the dissolution test, instructions for crushing the tablets can be provided with distributed batches.

¹³ This document is available at <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074927.htm>