

PRM 35-19
(71FR34285)

August 7, 2006 (7:50am)

From: David Diamond <dagdmail@yahoo.com>
To: Mohammad Saba <MSS@nrc.gov>, <suleimano@cder.fda.gov>, <reschenter@comcast.net>, <vetter.richard@mayo.edu>, <edbaileychp@msn.com>, <nag.1@osu.edu>, <degli@psu.edu>, <DPavone@psu.edu>, <lietor@trinity-health.org>, <malmudls@tuhs.temple.edu>, <vandecwa@tuhs.temple.edu>, <jfwilliamson@vcu.edu>
Date: Thu, Aug 3, 2006 7:47 AM
Subject: Re: Published FRN Attached for Your Information/Stein Petition

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Mr Saba and ACMUI Colleagues:

As you know, I will no longer be a seated member of the ACMUI as of the Fall, 2006, meeting when the rulemaking petition submitted by Dr Stein will be discussed.

I, therefore, would like to go on record to express my strong opinion against extending AU status to medical oncologists and hematologists for the purpose of parenteral administration of unsealed radioisotopes in the context of radioimmunotherapy (RIT).

There is no public need (ie, access to medical care) nor safety issue that would warrant such rulemaking consideration.

Over the last several years, the ACMUI has recognized the several instances where it was considered reasonable for the public interest and safe (predicated upon background training & experience) for AU status for a given modality to be expanded to additional users.

In all such cases that I am aware of from my 6-plus years of involvement with the ACMUI, these were instances of users/medical specialty groups whose backgrounds had included extensive didactic and clinical training & experience with therapeutic radioactive materials. An appropriate example would be the ACMUI's recognition--and thus the resultant rulemaking change--that appropriately trained nuclear medicine physicians would be expected (as has been the case with appropriately trained radiation oncologists) to safely administer RIT agents.

It must be clearly enunciated that no such extensive background exists with those medical professional who have or are currently undergoing training in medical oncology/hematology.

Thank you,
David Diamond, MD

Mohammad Saba <MSS@nrc.gov> wrote:
Dear ACMUI Member:

I have attached the following published FRNs for your information:

1. Federal Register Notice for the petition for rulemaking filed by William Stein III, MD.
2. Federal register Notice for NARM rulemaking.

If you have any questions or concerns, please contact me either by phone or via e-mail. Thank you.

Mohammad Saba

Template = SECY-067

SECY-02

CC: Cynthia Flannery <CMF@nrc.gov>

Mail Envelope Properties (44D26775.5DA : 23 : 35244)

Subject: Fwd: Re: Published FRN Attached for Your Information/Stein Petition
Creation Date 08/03/2006 5:15:33 PM
From: Mohammad Saba
Created By: MSS@nrc.gov

Recipients

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OWGWPO02.HQGWDO01
 CMF CC (Cynthia Flannery)

nrc.gov

TWGWPO01.HQGWDO01
 MTL (Michael Lesar)

Post Office

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Route

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MESSAGE
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Size
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Date & Time

08/03/2006 5:15:33 PM

Options

Expiration Date: None
Priority: Standard
ReplyRequested: No
Return Notification: None

Concealed Subject: No
Security: Standard

Junk Mail Handling Evaluation Results

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 Message is from an internal sender

Junk Mail settings when this message was delivered

Junk Mail handling disabled by User
 Junk Mail handling disabled by Administrator
 Junk List is not enabled
 Junk Mail using personal address books is not enabled
 Block List is not enabled

From: Mohammad Saba
To: Michael Lesar
Date: Thu, Aug 3, 2006 5:15 PM
Subject: Fwd: Re: Published FRN Attached for Your Information/Stein Petition

Michael Lesar:

I am forwarding the comment from Dr. David Diamond on the petition by William Stein, MD (PRM-35-19) that was published in the FR on June 14, 2006 to you to be considered. Dr. Diamond has served more than six years on the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

If you have any questions or concerns, please contact me either by phone or via e-mail. Thank you.

Mohammad Saba
PM for ACMUI
Phone:301-415-7608

CC: Cynthia Flannery

Mail Envelope Properties (44D3268F.7FE : 2 : 34858)

Subject: Fwd: Re: Published FRN Attached for Your Information/Stein Petition
Creation Date 08/04/2006 6:50:55 AM
From: Michael Lesar
Created By: MTL@nrc.gov

Recipients

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OWGWPO02.HQGWDO01
 ELJ (Emile Julian)

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 ESN (Evangeline Ngbea)

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Size**Date & Time****Options**

Expiration Date: None
Priority: Standard
ReplyRequested: No
Return Notification: None

Concealed Subject: No
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