*Drug Information*

Rifampin Dosage Forms

- *Intravenous:* 600 mg Rifampin, sodium formaldehyde sulfoxylate 10mg, and sodium hydroxide to adjust pH.
- *Oral:* 150 mg or 300 mg capsules can be compounded as per FDA-approved package labeling to a concentration of 10mg/ml oral suspension.

Route of Administration. Initially, intravenous in all studies with protocol-specified switch to oral formulation of rifampin based on protocol-specified criteria (*e.g.*, after the patient has stabilized and can tolerate oral administration).

*Drug Specific Safety Concerns*

Routine safety assessments, such as vitals signs, weight, serum chemistry, and monitoring for adverse events must be collected at baseline and at intervals throughout the study. Monitoring should be appropriate for detecting adverse events, including but not limited to hepatotoxicity, renal toxicity, hemolytic anemia, gastrointestinal effects, and seizures. Subjects should be maintained on protocol-specified monitoring even if the experimental or control regimen is discontinued, *i.e.*, consenting subjects should remain on study regardless of therapeutic course after enrollment. Compliance and drug status (*i.e.*, whether the subject is on or off protocol-specified therapy) must be monitored throughout the study. All efforts should be made to minimize loss to follow-up of study patients.

*Statistical Information, Including Power of Study and Statistical Assessment*

The study must have a detailed pre-specified statistical analysis plan appropriate to the study design and outcome measures. The study must be adequately powered (at least 80% power) to detect a statistically significant treatment effect on the primary endpoint at a significance level of $p < 0.05$ (two sided test) for each stratum, *i.e.*, (a) native valve endocarditis due to methicillin-resistant S. aureus, and (b) prosthetic material endocarditis due to methicillin resistant S. aureus or coagulase-negative staphylococci. If two separate studies are submitted, each will be properly powered for the primary endpoint. The assumptions for the sample sizes proposed in the protocol should be clearly stated with appropriate references. Interim analyses should also be included, as should the role of a Data Safety and Monitoring Board.

Descriptions of the PK parameters to be obtained must be provided. Demographic and safety data will be tabulated, and a descriptive analysis of safety data will be provided.

*Labeling Changes That May Result From These Studies*

Appropriate sections of the rifampin product labeling may be altered to incorporate the findings of these studies, including recommended pediatric dosing, treatment of endocarditis, pediatric pharmacokinetics, and safety information in children.

*Format of Reports To Be Submitted*

Full study reports with analysis, assessment, and interpretation, not previously submitted to the Agency addressing the issues outlined in this request will be submitted. Pharmacokinetic study reports should include analytical method and assay validation, individual drug and/or metabolite concentration-time data and individual pharmacokinetic parameters.

In addition, the reports are to include information on the representation of pediatric patients of ethnic and racial minorities. All pediatric patients enrolled in the study(s) must be categorized using one of the following designations for race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander or White. For ethnicity one of the following designations must be used: Hispanic/Latino or Not Hispanic/Latino.

*Time Frame for Submitting Reports of the Studies*

Reports of the above studies must be submitted to the Agency on or before September 30, 2007. Please keep in mind that pediatric exclusivity attaches only to existing patent protection or exclusivity that has not expired at the time you submit your reports of the studies in response to this Written Request.

*Response to Written Request*

As per the Best Pharmaceuticals for Children Act, Section 3, if we do not hear from you within 30 days of the date of this Written Request, we will refer this Written Request to the Director of the NIH. If you agree to the request, then you must indicate when the pediatric studies will be initiated.

Please submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission ''PEDIATRIC PROTOCOL SUBMITTED IN RESPONSE TO WRITTEN REQUEST'' in large font, bolded type at the beginning of the cover letter of the submission. Please notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Clearly mark your submission ''PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES'' in large font, bolded type at the beginning of the cover letter of the submission.

Reports of the studies should be submitted as a new drug application (NDA) or as a supplement to an approved NDA with the proposed labeling changes you believe would be warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission ''SUBMISSION OF PEDIATRIC STUDY REPORTS—COMPLETE RESPONSE TO WRITTEN REQUEST'' in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter.

If you wish to discuss any amendments to this Written Request, please submit proposed changes and the reasons for the proposed changes to your application. Submissions of proposed changes to this request should be clearly marked ''PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES'' in large font, bolded type at the beginning of the cover letter of the submission. You will be notified in writing if any changes to this Written Request are agreed to by the Agency.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits in the pediatric population.

If you have any questions, call NAME, Project Manager, at PHONE NUMBER.

[FR Doc. 04–11063 Filed 5–14–04; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[USCG–2004–17768]**

### Chemical Transportation Advisory Committee

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of open teleconference meeting.

**SUMMARY:** This notice announces a teleconference meeting of the Subcommittee of the Chemical Transportation Advisory Committee (CTAC) on the National Fire Protection

Association (NFPA) 472 Standard. The NFPA 472 Subcommittee will meet to discuss the formation of a marine emergency responder chapter in NFPA 472, Professional Competence of Responders to Hazardous Materials Incidents. This meeting will be open to the public.

**DATES:** The teleconference call will take place on Thursday, June 10, 2004, from 9 a.m. to 11 a.m. EST. Written comments may be submitted on or before June 9, 2004.

**ADDRESSES:** Members of the public may participate by coming to Room 2100, U.S. Coast Guard Headquarters Building, 2100 Second Street, SW., Washington, DC 20593. We request that members of the public who plan to attend this meeting notify LT Matt Barker at 202 267–1217 so that he may notify building security officials. Written comments should be sent to CDR Robert J. Hennessy, Executive Director, CTAC, Commandant (G–MSO–3), 2100 Second Street, SW., Washington DC 20593–0001 or Fax: 202 267–4570. This notice is available on the Internet at *http://dms.dot.gov.*

**FOR FURTHER INFORMATION CONTACT:** Commander Robert J. Hennessy, Executive Director of CTAC, or Ms. Sara Ju, Assistant to the Executive Director, telephone 202 267–1217, fax 202 267–4570.

**SUPPLEMENTARY INFORMATION:** Members of the public may participate by dialing 202 366–3920, Passcode: 5999. Public participation is welcomed; however, the number of teleconference lines is limited and available on a first-come, first-served basis. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

**Tentative Agenda**

(1) Introduction of Subcommittee members and public attendees.

(2) Review of the initiative to incorporate marine specific competencies, for hazardous material incident responders, into the NFPA 472 Standard.

(3) Discussion on draft chapter for future incorporation into the NFPA 472.

(4) Discussion on the formation of Workgroups within the Subcommittee that will be tasked to write specific parts of the draft chapter.

(5) Public comment period.

**Public Participation**

The Chairman of this NFPA 472 Subcommittee shall conduct the teleconference in a way that will, in his judgment, facilitate the orderly conduct of business. During the teleconference, the Subcommittee welcomes public comment. Members of the public will be heard during the public comment period. The committee will make every effort to hear the views of all interested parties. Please note that the teleconference may close early if all business is finished. Written comments may be submitted on or before the day of the teleconference (see **ADDRESSES**).

**Minutes**

The teleconference will be recorded, and a summary will be available for public review and copying in the docket approximately 30 days following the teleconference meeting.

Dated: May 7, 2004.

**Joseph J. Angelo,**

*Director of Standards, Marine Safety, Security and Environmental Protection.*

[FR Doc. 04–11146 Filed 5–14–04; 8:45 am]

**BILLING CODE 4910–15–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[USCG–2004–17767]**

### Chemical Transportation Advisory Committee

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Subcommittee of the Chemical Transportation Advisory Committee (CTAC) on Hazardous Cargo Transportation Security will meet to discuss the potential addition of acrylonitrile to the Certain Dangerous Cargoes (CDC) definition and to review recent workgroup discussions and outcomes regarding CDC mixtures and the Declaration of Security. This meeting will be open to the public.

**DATES:** The CTAC Subcommittee on Hazardous Cargo Transportation Security will meet on Tuesday, June 8, 2004, from 8 a.m. to 4 p.m. and Wednesday, June 9, 2004, from 8 a.m. to 4 p.m. These meetings may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before June 4, 2004. Requests to have a copy of your material distributed to each member of the Subcommittee should also reach the Coast Guard on or before June 4, 2004.

**ADDRESSES:** The Subcommittee on Hazardous Cargo Transportation Security will meet at the Department of Transportation Headquarters, Nassif Building, L'Enfant Plaza, 400 7th Street, SW., Washington, DC, in room 6244. Send written material and requests to make oral presentations to Commander Robert J. Hennessy, Executive Director of CTAC, Commandant (G–MSO–3), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593–0001. This notice is available on the Internet at *http://dms.dot.gov.*

**FOR FURTHER INFORMATION CONTACT:** Commander Robert J. Hennessy, Executive Director of CTAC, telephone (202) 267–1217 or fax (202) 267–4570.

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2 (Pub. L. 92–463, 86 Stat. 770, as amended).

**Agenda of Subcommittee Meeting on June 8, 2004**

Discuss potential addition of acrylonitrile to the CDC definition.

**Agenda of Subcommittee Meeting on June 9, 2004**

Review recent workgroup discussions and outcomes regarding CDC mixtures and the Declaration of Security.

**Procedural**

These meetings are open to the public. Please note that the meetings may close early if all business is finished. At the discretion of the Chair, members of the public may make oral presentations during the meetings. If you would like to make an oral presentation at a meeting, please notify the Executive Director and submit written material. If you would like a copy of your material distributed to each member of the Committee in advance of a meeting, please submit 25 copies to the Executive Director (*see* **ADDRESSES** and **DATES**).

**Information on Services for Individuals With Disabilities**

For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, telephone the Executive Director as soon as possible.

Dated: May 10, 2004.

**Joseph J. Angelo,**

*Director of Standards, Marine Safety, Security and Environmental Protection.*

[FR Doc. 04–11147 Filed 5–14–04; 8:45 am]

**BILLING CODE 4910–15–P**