Drug—Specific Safety Concerns (all studies):

1. It is unknown whether azithromycin has an adverse events profile similar to or different than that reported for erythromycin, with respect to infantile hypertrophic pyloric stenosis.

2. Colonization and infection with other bacterial (including macrolide-resistant organisms) and non-bacterial organisms (*e.g.* fungus) may occur with azithromycin treatment.

3. Macrolides have been associated with hearing loss at high doses. The potential for hearing loss with azithromycin treatment in this population will be assessed.

Safety (all studies): Safety assessments will include occurrence of any adverse events (AEs), incidence of superinfections (particularly fungal infections), vital signs that include heart rate , blood pressure, respiratory rate , pulse oximetry, standard laboratory assessments of hematologic, liver and renal function, assessments of hearing, and growth (weight, length and head circumference). AEs will be followed to their resolution or stabilization. Nosocomial infection will be tracked by pathogen.

Drug Information:

• Dosage Form: approved age appropriate oral formulations of azithromycin and erythromycin Route of Administration: oral

• Regimen: To be determined

Selection of doses for azithromycin in Study 1 will be guided by extrapolation of data from azithromycin use in older infants, published literature and/or current medical practice. Azithromycin doses chosen for Study 2 will be guided by the results of Study 1. For Studies 1 and 2, erythromycin dose will be based on current medical practice. Selection of azithromycin doses for Study 3 will be guided by the results of Studies 1 and 2. Azithromycin doses for Study 4 will be guided by the results of the first three studies.

Labeling that may result from the studies: Appropriate sections of the label may be changed to incorporate the findings of the studies.

Format of reports to be submitted: Full study reports not previously submitted to the Agency addressing the issues outlined in this request, with full analysis, assessment, and interpretation are required. Pharmacokinetic study reports will include analytical method and assay validation, individual drug concentration-time data and individual pharmacokinetic parameters (and pharmacodynamic data when available). 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 studies should 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.

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 upon 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.

[FR Doc. 04–23724 Filed 10–21–04; 8:45 am]

BILLING CODE 4167–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1545–DR]

Florida; Amendment No. 11 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Florida (FEMA–1545–DR), dated September 4, 2004, and related determinations.

EFFECTIVE DATE: October 8, 2004.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective October 8, 2004.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 04–23733 Filed 10–21–04; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1561–DR]

Florida; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–1561–DR), dated September 26, 2004, and related determinations.

EFFECTIVE DATE: October 14, 2004.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of September 26, 2004:

Collier, Lee, and Miami-Dade Counties for emergency protective measures (Category B) under the Public Assistance program.