Appendix M, Points To Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules Into One or More Human Subjects (Points To Consider)

Appendix M–VII–C, Serious Adverse Events, is proposed to read:

''Appendix M–VII–C–1, Serious Adverse Event Reporting

''Principal Investigators who have received authorization from FDA to initiate a human gene transfer protocol must report immediately in writing any serious adverse event (as defined in Section I–E–7) to the local Institutional Review Board, Institutional Biosafety Committee, Office for Protection from Research Risks (if applicable), NIH/ORDA, and FDA.

''Serious adverse event reports must not contain any trade secret or commercial or financial information that is privileged or confidential as defined under the Freedom of Information Act, 5 U.S.C. 552; therefore, unless NIH/ORDA determines that there are exceptional circumstances, all information submitted in accordance with Appendix M–VII–C will be considered public.

''Reports of serious adverse events may be submitted by e-mail to: ci4e@nih.gov, fax to: 301–496–9839, or by mail to: the Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010.

Appendix M–VII–C–2, Serious Adverse Event Reporting: Content and Format

''Reports of serious adverse events must follow the format provided in the Adverse Event Reporting Form available on NIH/ORDA's web site at: http://www.nih.gov/od/orda/. The serious adverse event report must include, but need not be limited to: (1) The date of the event; (2) a complete description of the event; (3) relevant clinical observations; (4) relevant clinical history; (5) relevant tests that were or are planned to be conducted; (6) the suspected cause of the event; (7) gene delivery method; (8) vector type, *e.g.*, adenovirus; (9) vector subtype, *e.g.*, type 5, relevant deletions; (10) dosing schedule; (11) route of administration; (12) clinical site; (13) principal investigator(s); (14) NIH Protocol number; and (15) Investigational New Drug (IND) number.

''Serious adverse event reports should be stripped of individually-identifiable patient information. Examples of such information include, but are not limited to, the patient's name, address, contact information, social security number, date of birth.

''Appendix M–VII–C–3, Time-Frames for Serious Adverse Event Reporting: Initial and Follow-Up Reports

''Immediate reporting of serious adverse events is essential for the early identification of acute events related to a gene transfer procedure, as well as the identification of patterns that may signal potential safety concerns. For the purposes of the NIH Guidelines, 'immediate' written reporting of all serious adverse events is to occur as soon as possible but no later than 15 calendar days after such an event has occurred. This applies to all serious adverse events, related or unrelated to gene transfer, which occur during the course of the clinical trial.

''Relevant additional clinical and laboratory data may become available following the initial serious adverse event report. The Principal Investigator(s) must provide any relevant follow-up information to a serious adverse event report within 15 calendar days of receipt of the relevant information. In addition, if a serious adverse event occurs after the end of a clinical trial, and is determined to be related to gene transfer, that event shall be reported by the Principal Investigator within 15 calendar days of the determination.''

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which recombinant DNA techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: November 16, 1999.

Lana Skirboll,

Associate Director for Science Policy, National Institutes of Health.

[FR Doc. 99–30342 Filed 11–19–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–066–99–1990–00; CACA–20139 and CACA–22901]

Notice of Availability of Supplemental Environmental Impact Statement and Preferred Action for the Proposed Sand and Gravel Mining Operation, Los Angeles County, CA

AGENCY: Bureau of Land Management, Department of the Interior, Palm Springs-South Coast Field Office, Desert District, California.

ACTION: Notice of availability of supplemental environmental impact statement and identification of preferred action.

SUMMARY: In compliance with the National Environmental Policy Act (NEPA) of 1969 and 40 CFR 1503.1(a), notice is hereby given that the Bureau of Land Management (BLM) has prepared a supplement to the Draft Environmental Impact Statement (EIS). This supplement to the Draft EIS addresses a new proposal by Transit Mixed Concrete Company to transport mine material by a conveyor belt system rather than open trucks as proposed in the original draft EIS. The supplement will provide; further analysis of the potential air quality impacts. In addition the supplement identifies the BLM's preferred action. Interested citizens are invited to review the Supplement and submit comments. Copies of the Supplement may be obtained by telephoning or writing to the contact person listed below. Public reading copies of the Supplement are available at the following County of Los Angeles public libraries: Canyon County Library, 18536 Soledad Canyon Road, Santa Clarita, CA 91351; Newhall Library, 22704 W. Ninth Street, Santa Clarita, CA 91321; Valencia Library, 23743 W. Valencia Boulevard, Santa Clarita, CA 91355.

DATES: Comments must be received in writing to the BLM no later than January 10, 2000.

ADDRESSES: Written comments shall be mailed to the following address: Mr. James G. Kenna, Field Manager, Bureau of Land Management, Palm Springs-South Coast Field Office, 690 W. Garnet Avenue, PO Box 1260, North Palm Springs, California, 92258. Comments may also be submitted by electronic mail (E-mail) to the following address: emisquez@ca.blm.gov. The response to comments will be provided in the Final EIS.

FOR FURTHER INFORMATION CONTACT: Ms. Elena Misquez, BLM, Palm Springs-South Coast Field Office, PO Box 1260, North Palm Springs, CA 92258, telephone 760–251–4804.

Dated: November 12, 1999.

Carole Levitzky,

Assistant District Manager, External Affairs.

[FR Doc. 99–30094 Filed 11–19–99; 8:45 am]

BILLING CODE 4310–40–M