its major metalbolite, norpropoxyphene, that are associated with death, and what is the relationship of these levels to those observed when the drug is taken at recommended doses? What is the mechanism of death in these cases? Is it only respiratory depression, or is there a previously unrecognized effect on cardiac conduction? Are there differences in risk among DPX-containing salts and combinations?

2. Is there "lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof"? (21 CFR 314.115(b)(3)). Specifically, is there scientific evidence that DPX contributes to the analgesic effect of combination products containing aspirin, acetaminophen, or APC, as required by the FDA fixed-combination policy? (21 CFR 300.50(a)). Are there any differences in effectiveness or other benefits among particular salts or combinations of DPX?

In addition, the agency is interested in receiving testimony on whether additional regulatory action is needed at this time with respect to DPX-containing products. Such action could include, but is not necessarily limited to, removal of some or all of these products from the market, rescheduling under the Controlled Substances Act to Schedule III or II, the placing of new warnings in the labeling for physicians or a limitation in the labeling to use in patients who cannot tolerate other analgesics, and/or providing patients with warnings or other information. In a related, though separate, proceeding, the issue of whether DPX should be placed in Schedule II of the Controlled Substances Act, 21 U.S.C. 801 et seq. is being considered by the FDA's Drug Abuse Advisory Committee, which held an initial meeting on the subject on February 13, 1979 and will hold its second and final such meeting on April 17, 1979 to enable FDA to meet a June 1, 1979 deadline set by the Secretary of Health, Education, and Welfare for recommendations on scheduling of DPX. Because that issue is being fully considered in that particular context, it is requested that participants at this hearing not focus primarily on the scheduling issue.

The record of another related proceeding, the testimony at the propoxyphene hearings on January 31, February 1 and 5, 1979 of the Monopoly and Anticompetitive Activities Subcommittee of the Select Committee on Small Business of the U.S. Senate, is already the subject of review and study by FDA. For that reason, it will be unnecessary for participants to duplicate any of that testimony at this hearing.

The hearing will begin at 9 a.m. on April 6, 1979, in the Snow Room (Room 5051), HEW North Building, 330 Independence Ave., SW., Washington, D.C. The presiding officer will be Ronald Kartzinel, M.D., Ph. D., Director of the Division of Neuropharmacological Drug Products, Bureau of Drugs, FDA.

Persons wishing to comment or present views at the hearing must file by March 23, 1979, a written notice of participation under 21 CFR 15.21 with the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857. The Envelope containing the notice should be prominently marked "Propoxyphene Hearing." The notice of participation should contain the following: Hearing Clerk Docket No. 77N-0266; the name, address and telephone number of the person desiring to make a statement; business or professional affiliation, if any; the subject of the presentation; and the approximate amount of time being requested for the presentation.

A notice of participation may be telephoned to Mr. Robert Nelson, 301-443-3800 by persons who find there is insufficient time to submit the required information in written form.

Individuals and organizations with common interests are urged to consolidate or coordinate their presentations. The agency may require joint presentations by persons with common interests. It will allocate the time available for the hearing among the persons who properly file a notice of participation and will make a schedule of the hearing available to those persons. Persons may use their allotted time on any aspect of the proposed action, consistent with the conduct of a reasonable and orderly hearing. Formal written statements on the issues may be presented to the presiding officer on the day of the hearing for inclusion in the record. The time available for the hearing may make it impossible to accomodate all those desiring to appear. The Commissioner encourages those not appearing in person to submit their information in written form for inclusion in the administrative record of the drug.

The hearing will be open to the public. At the discretion of the presiding officer, and as time permits, any interested person in attendance may speak on matters relevant to the issue under consideration after scheduled parties have presented their views.

In order to permit time for all interested persons to submit data, information, or views, on the subject matter of the hearing, the administrative record of the public hearing will remain open for 45 days after the hearing is held.

Dated: February 26, 1979.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 79-6246 Filed 3-1-79; 8:45 am]

[4310-02-M]

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

RECEIPT OF PETITION FOR FEDERAL ACKNOWLEDGMENT OF EXISTENCE AS AN INDIAN TRIBE

This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 230 DM 2.

Pursuant to 25 CFR 54.8(a) notice is hereby given that the Jena Band of Choctaw Indians, c/o Mr. Clyde Jackson, Post Office Box 212, Trout, Louisiana 71371, has filed a petition for acknowledgment by the Secretary of the Interior that the group exists as an Indian tribe. The petition was received by the Bureau of Indian Affairs on February 1, 1979. The petition was forwarded and signed by Mr. Clyde Jackson, Chairman of the petitioning group.

This is notice of receipt of petition and does not constitute notice that the petition is under active consideration. Notice of active consideration will be mail to the petitioner and other interested parties at the appropriate time.

Under Section 54.8(d) of the Federal regulations, interested parties may submit factual or legal arguments in support of or in opposition to the group's petition. Any information submitted will be made available on the same basis as other information in the Bureau of Indian Affairs files.

The petition may be examined by appointment in the Division of Tribal Government Services, Bureau of Indian Affairs, Department of the Interior, 18th and C Street, N.W., Washington, D.C. 20245.

FORREST J. GERARD,
Assistant Secretary—
Indian Affairs.

FEBRUARY 27, 1979.

[FR Doc. 79-6302 Filed 3-1-79; 8:45 am]

[4310-02-M]

RECEIPT OF PETITION FOR FEDERAL ACKNOWLEDGMENT OF EXISTENCE AS AN INDIAN TRIBE

FEBRUARY 27, 1979.

This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 230 DM 2.

Pursuant to 25 CFR 54.8(a) notice is hereby given that the Mashantucket