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NO

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071600Z APR 79

USAFMEDCEN WPAFB OH/SGHR

U.S. NUCLEAR REGULATORY COMMISSION, LICENSE  
MANAGEMENT BR, WASH DC 20555

TX 7108240415

INFO HQ AMB/SGZ, USAF RADIOISOTOPE COMMITTEE,  
BROOKS AFB TX 78235

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AT U.S. NUCLEAR REGULATORY COMMISSION FOR DR. W. WALKER JR. OR  
MRS. P. VACCA.

SUBJECT: EMERGENCY REQUEST FOR AMENDMENT TO BYPRODUCT MATERIAL  
LICENSE

THIS MESSAGE IN SEVEN (7) PARTS.

PART 1. REQUEST AN EMERGENCY AMENDMENT TO U.S. NUCLEAR REGULATORY  
COMMISSION BYPRODUCT MATERIAL LICENSE NO. 34-04682-01 ISSUED TO USAF  
MEDICAL CENTER, WRIGHT-PATTERSON AFB, OHIO 45433.

PART 2. AMENDMENT IS FOR ONE (1) TIME USE OF COPPER-64 IN THE FORM  
OF CUPRIC ACETATE SOLUTION IN THE AMOUNT OF TWO (2) MILLICURIES TOTAL  
POSSESSION LIMIT FOR ADMINISTRATION TO A PATIENT WITH WILSON'S  
DISEASE. AMOUNT TO BE ADMINISTERED TO PATIENT IS APPROXIMATELY ONE

AIR1.941130.052kd

FRANCIS J. CONNOLLY, MAJ, USAF, SGHRT  
RADIATION PHYSICIST, 74B59

BARBARA ANDRES, SSGT, USAF  
BCOIC, ADMIN SERVICES

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{1} MILLICURIE CONTAINING APPROXIMATELY ONE {2} TO TWO {2} MILLIGRAMS OF COPPER. PATIENT WILL BE ADMINISTERED THE RADIOPHARMACEUTICAL PER ORA IN A MIXTURE OF MILK. TWO {2} HOURS POST-ADMINISTRATION, PATIENT WILL BE TAKEN TO THE OPERATING ROOM FOR LIVER BIOPSY, SPLENECTOMY, AND SPLENO-RENAL SHUNT.

PART 3. RADIOPHARMACEUTICAL IS USED FOR CLINICAL RESEARCH AND DIAGNOSIS BY I. HERBERT SCHEINBERG, M.D., PROFESSOR OF MEDICINE, HEAD, DIVISION OF GENETIC MEDICINE, ALBERT EINSTEIN COLLEGE OF MEDICINE, BRONX, NEW YORK. DR. SCHEINBERG WILL BE CONSULTING ON THE CASE AND WILL ADMINISTER THE RADIOPHARMACEUTICAL TO THE PATIENT UNDER APPROVAL AND/OR SUPERVISION OF PHYSICIANS APPROVED BY THE USAF MEDICAL ISOTOPE COMMITTEE, WRIGHT-PATTERSON AFB. DR. SCHEINBERG WILL ALSO PERFORM THE NECESSARY RIA STUDIES OF THE LIVER BIOPSY.

PART 4. THE USE OF THIS RADIOPHARMACEUTICAL HAS BEEN APPROVED VIA TELEPHONE CONVERSATION WITH DR. MARTIN NISSEL, FOOD AND DRUG ADMINISTRATION, WASHINGTON, D.C. (TELEPHONE 301-443-4260) ON 6 APRIL 1977. FDA HAS ISSUED AN EMERGENCY IND (INVESTIGATIONAL NEW DRUG) PERMIT NO. 16300 TO THE USAF MEDICAL CENTER, WRIGHT-PATTERSON AFB FOR THIS ONE TIME USE OF COPPER-64 CUPRIC ACETATE. FDA IND PERMIT NO. 16300

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EXPECTED TO ARRIVE THIS MEDICAL CENTER ON 9 APRIL 1979.

PART 5. THE USE OF THIS RADIOPHARMACEUTICAL HAS BEEN COORDINATED WITH CAPTAIN JOHN RICCI, ACTING SECRETARY, USAF RADIOISOTOPE COMMITTEE, BROOKS AFB, TX ON 6 APRIL 1979. CAPT RICCI HAS APPROVED DIRECT COMMUNICATION BY THIS MEDICAL CENTER WITH THE U.S. NUCLEAR REGULATORY COMMISSION ON THIS MATTER.

PART 6. ADMINISTRATION OF THIS RADIOPHARMACEUTICAL AND ASSOCIATED SURGICAL PROCEDURES IS SCHEDULED FOR EARLY MORNING OF THURSDAY 12 APR 1979. REQUEST THAT THIS MATTER RECEIVE YOUR IMMEDIATE ATTENTION.

PART 7. RADIATION SAFETY AND MONITORING OF PATIENT, SURGICAL TEAM AND CONTAMINATED OBJECTS TO BE PERFORMED BY MEDICAL CENTER RADIATION PROTECTION OFFICER, MAJOR FRANCIS J. CONNOLLY. QUESTIONS CONCERNING THIS MATTER SHOULD BE ADDRESSED TO MAJOR CONNOLLY AT TELEPHONE 513-257-4159 OR 257-3562.

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