hds human development services	U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Administration on Developmental Disabilities	
	1. Log No. ADD-IM-85- 7	2. Issuance Date: 7/30/85
	3. Originating Office: Administration on Developmental Disabilities	
	4. Key Word: FY 1985 Reallotment	5. Formula Grants
	6.	7.

INFORMATION MEMORANDUM

TO: Directors, State Administering Agencies
Executive Directors, State Planning Councils
Chairpersons, State Planning Councils
Directors, State Protection and Advocacy Agencies

SUBJECT: Federal Register "Notice of Intent to Reallot Basic Support and Protection and Advocacy Funds to States for Developmental Disabilities"

CONTENT: Attached is a copy of the Administration on Developmental Disabilities' Notice of intent to reallot Developmental Disabilities Formula Grant funds for Fiscal Year 1985 published in the Federal Register on July 18, 1985.

Also attached is a table that gives the tentative reallotment of funds based on the allotment of the Trust Territory of the Pacific Islands, a non-participating jurisdiction. If any State(s) indicates in writing that it will not be able to use all the funds already provided to them, such amounts will be similarly reallotted. In order for a State to receive a reallotment, the written notice must be submitted no later than August 19, 1985 (30 days from date of the Federal Register publication).

Avenue SW., Room 341F.4 HHH Bldg., Washington, D.C. 20201.

If a State fails to provide written notice as indicated above by August 19, 1985, that State will not receive additional funds under the fiscal year 1985 reallocation of funds.

FOR FURTHER INFORMATION CONTACT: Bettye J. Mobley, (202) 245-7220.

(Catalog of Federal Domestic Assistance Program No. 13-630 Developmental Disabilities-Basic Support and Advocacy Grants)

Dated: July 11, 1985.

Jean K. Elder,

Commissioner, Administration on Developmental Disabilities.

Approved: July 15, 1985.

[FR Doc. 85-17094 Filed 7-17-85; 8:45 am]

BILLING CODE 4130-01-M

National Institutes of Health

Developmental Therapeutics Contracts Review Committee; Cancellation of Meeting

Notice of the meeting of the Developmental Therapeutics Contracts Review Committee, National Cancer Institute, National Institutes of Health, July 26, 1985, published in the Federal Register, (50 FR 25629) is hereby cancelled as fewer applications were received than expected. Therefore, it will be possible to review all applications within the time frame of the July 29-30 meeting. For further information, please contact Dr. Kendall G. Powers, Executive Secretary, National Cancer Institute, Westwood Building, Room 605, National Institutes of Health, Bethesda, Maryland 20205 (301/496-7575).

Dated: July 10, 1985.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 85-17035 Filed 7-17-85; 8:45 am]

BILLING CODE 4140-01-M

Commercial/Industrial Activities Review Schedule

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice of Review Schedule.

SUMMARY: This notice identifies a cost comparison study for a commercial/industrial activity by the National Institutes of Health during Fiscal Year 1986. This study will be in accordance with Office of Management and Budget Circular A-76.

FOR FURTHER INFORMATION CONTACT: Ana Kennedy, Division of Management Policy, National Institutes of Health, Building 31, Room 2B19, 9000 Rockville Pike, Bethesda, Maryland 20205, (301) 496-2461.

SUPPLEMENTARY INFORMATION: In accordance with OMB Circular A-76, a cost comparison is scheduled for the elevator maintenance and related services to be completed by January 1986. This activity includes administration, maintenance, repair, inspections and emergency service work for elevators, escalators, dumbwaiters, automatic doors, window washing scaffolds and automated materiel handling systems.

The activity is located at the National Institutes of Health, Bethesda, Maryland.

Dated: July 9, 1985.

James B. Wyngaarden,

Director, National Institutes of Health.

[FR Doc. 85-17033 Filed 7-17-85; 8:45 am]

BILLING CODE 4140-01-M

Public Health Service

National Toxicology Program; Availability of Technical Report on Toxicology and Carcinogenesis Studies of Telone II®

The HHS' National Toxicology Program today announces the availability of the technical report described toxicology and carcinogenesis studies of Telon II® (Technical-Grade 1,3-Dichloropropene containing 1.0% epichlorohydrin as a Stabilizer). Telone II® is widely used in agriculture as a soil fumigant for parasitic plant nematodes. 1,3-Dichloropropene, a mixture of *cis and trans* isomers, is a clear, light straw-colored liquid with a penetrating, irritating, chloroform-like odor and is also found in D-D® and Vorlex® soil fumigants.

Toxicology and carcinogenesis studies of Telone II® were conducted by administering the commercial-grade forumlation in corn oil by gavage to groups of 52 male and 52 female F334/N rats at does of 0, 25, or 50 mg/kg and to groups of 50 male and 50 female B6C3F$_1$ mice at doses of 0, 50, or 100 mg/kg. Doses were administered three times per week for 104 weeks. Ancillary studies were conducted in which dose groups containing five male and five female rats were killed after Telone II® for 9, 18, 21, 24, or 27 months.

Under the conditions of these gavage studies, there was *clear evidence of carcinogenicity* for male F344/M rats, as indicated by Telone II®-related increased incidence of squamous cell papillomas and caricinomas of the forestomach, as well as an increased incidence of neoplastic nodules of the liver. In femal F334/N rats, there was *some evidence of carcinogenicity* because Telone II® caused an increased incidence of squamous cell papillomas of the forestomach. The experiment in male B6C3F$_1$ mice was considered to be an *inadequate study of carcinogenicity* because of reduced survival in the vehicle control group. However, there was some indication in the male mice of Telone II®-related increases of transitional cell carcinomas of the urinary bladder, squamous cell papillomas of the forestomach, and alveolar/bronchiolar adenomas and carcinomas of the lung. There was *clear evidence of carcinogenicity* for female B6C3F$_1$ mice, since Telone II® caused increased incidences of transitional cell carcinomas of the urinary bladder; Telone II® also increased the incidences of alveolar/bronchiolar adenomas of the lung and of squamous cell papillomas or carcinomas of the forestomach in the female mice. Telone II®-related non-neoplastic lesions included basal cell or hyperplasia in the forestomach of male and femal rats and male and female mice and epithelial hyperplasia of the urinary bladder in male and famale mice.

Copies of *Toxicology and Carcinogenesis Studies of Telone II®* in F344/N Rats and B6C3F$_1$ *Mice (Gavage Studies)* (*T.R. 269*) are available without charge from the NTP Public Information Office, M.D. B2-04, P.O. Box 12233, Research Triangle Park, NC, 27709. Telephone (919) 541-3991, FTS: 629-3991.

Dated: July 10, 1985.

David P. Rall,

Director.

[FR Doc. 85-17034 Filed 7-17-85; 8:45 am]

BILLING CODE 4101-01-M

Privacy Act of 1974; System of Records

AGENCY: Department of Health and Human Services, (HHS); Public Health Service, (PHS).

ACTION: Notification of establishment of a new Privacy Act system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Office of the Assistant Secretary for Health (OASH) is publishing notice of a proposal to establish a new Privacy Act system of records 09-37-0017, "Proceedings of the Board for Correction of Public Health Service Commissioned Corps Records, HHS/OASH/OM." This system, which has been a subsystem under another system of records, will continue to be used to review and act on requests to correct alleged errors or

[Docket No. 81D-0309]

Anti-Infective Bovine Mastitis Product Development; Availability of Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guideline entitled "Guideline for Anti-Infective Bovine Mastitis Product Development" prepared by FDA's Center for Veterinary Medicine (CVM). The guideline describes the type of data required to establish target animal safety and effectiveness of anti-infective drugs used for treatment and control of infectious bovine mastitis. This guideline is a revision of a 1981 draft guideline entitled "Antimicrobial Drugs for Intramammary Infusion" which described such required data. The agency is issuing the revised guideline under a different title to be consistent with current terminology.

ADDRESS: The draft and final revised guideline and comments are available for public examination at, further written comments may be submitted to, and requests for single copies may be sent to, the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Donald A. Gable, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: The Federal Food, Drug, and Cosmetic Act (the act) requires that a new animal drug be the subject of an approved new animal drug application (NADA) before it may be marketed in interstate commerce. Section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)) requires that each NADA include full reports of investigations that show that the drug is safe and effective for use. Section 512(d) of the act (21 U.S.C. 360b(d)) describes the criteria that must be met before a new animal drug may be approved, including that it be safe and effective for use as labeled. Section 514.1(b)(8) of the animal drug regulations (21 CFR 514.1(b)(8)) describes the effectiveness requirements for an NADA.

In the Federal Register of October 9, 1981 (46 FR 50152), FDA published a notice of availability of a draft revised guideline concerning the evaluation of antimicrobial drugs for intramammary infusion (infectious bovine mastitis) as related to target animal safety and effectiveness. The notice solicited comments by December 7, 1981. FDA published a notice in the Federal Register of December 4, 1981 (46 FR 59309), extending the time for comment to February 5, 1982, based on a request by the Animal Health Institute (AHI) in a letter dated November 3, 1981 (on file with the Dockets Management Branch).

In a letter dated February 4, 1982 (on file with the Dockets Management Branch), AHI requested a further extension of time and a meeting with CVM to discuss the guideline. CVM believed it would be beneficial to hold an open public meeting, and FDA published a notice in the Federal Register of March 2, 1982 (47 FR 8857), announcing a meeting to be held on May 19, 1982, in Rockville, MD, and extending the time for comment to July 6, 1982. The meeting was held and is summarized in memoranda that are on file with the Dockets Management Branch.

Twelve letters containing comments were received from drug manufacturers, professional organizations, the AHI, and the National Mastitis Council. A summary of the significant comments and the agency's responses is on file with the Dockets Management Branch.

The guideline replaces a guideline entitled "Guideline for Bovine Anti-Mastitis Products: 1973 Revised."

This notice of availability is issued under 21 CFR 10.90(b), which provides for use of guidelines to establish procedures of general applicability that are not legal requirements but are acceptable to the agency. Sponsors may rely upon a guideline with the assurance that it represents procedures acceptable to the agency (see 21 CFR 10.90). If a sponsor believes that alternative procedures are also applicable, a guideline does not preclude a sponsor from pursuing the alternative procedures. Under such circumstances, however, the agency encourages sponsors to discuss the alternative procedures in advance with FDA to prevent the expenditure of money and effort for work that may later be found unacceptable.

Interested persons may, at any time, submit additional written comments on the guideline to the Dockets Management Branch. Such comments will be considered in determining if further revisions of the guideline are required. Respondents should submit two copies (except that individuals may submit single copies) identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch from 9 a.m. to 4 p.m., Monday through Friday.

Dated: July 11, 1985.

Marvin H. Shumate,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-17020 Filed 7-17-85; 8:45 am]

BILLING CODE 4160-01-M

Captan With Benzocaine (Holiday® Itch Aid and VIP® Mercaptol); Withdrawal of Approval of NADA

Correction

In FR Doc. 85-15788 beginning on page 27360 in the issue of Tuesday, July 2, 1985, make the following correction:

On page 27361, first column, third line, "[21 U.S.C. 350(e)]" should read "[21 U.S.C. 360b(e)]".

BILLING CODE 1505-01-M

Office of Human Development Services

Intent To Reallot Basic Support and Protection and Advocacy Funds to States for Developmental Disabilities Expenditures

AGENCY: Administration on Developmental Disabilities, Office of Human Development Services, HHS.

ACTION: Notice of intent to reallot funds.

SUMMARY: The Administration on Developmental Disabilities herein gives notice of intent to reallot funds which will not be used by the Trust Territories of the Pacific and any other States prior to September 30, 1985, in accordance with section 125(d) of the Developmental Disabilities Assistance and Bill of Rights Act of 1984, Pub. L. 98-527. To be considered for receipt of additional funds under this reallotment, each State must provide the following information in writing:

(1) The amount of funds that will not be obligated prior to September 30, 1985, under its approved State Plan. If all funds will be obligated, provide a statement to that effect;

(2) If additional funds could be used and obligated prior to September 30, 1985; or

(3) A statement that no additional funds are needed.

The information provided will be used to calculate the amounts to be reallotted and this information should be submitted no later than (30 days from date of publication) to: Betty J. Mobley, Grants and Contracts Management Division, Office of Human Development Services, Department of Health and Human Services, 200 Independence

INQUIRIES TO: Bettye Mobley
Chief, Formula Grants Management Branch
Division of Grants and Contracts Management
Office of Management Services
Telephone: (202) 245-7220

Jean K. Elder, Ph.D.
Commissioner
Administration on Developmental
Disabilties

Attachments

cc: Regional Administrators, HDS, Regions III, VI, VII, IX
Regional Program Directors, ADD, Regions III, VI, VII, IX

FY 1985 ADD TENTATIVE REALLOTMENT
(Reallotment of Trust Territory Funds to Other Grantee)

	Basic Support	Protection and Advocacy
Alabama	4,045	1,435
Alaska	1,185	878
American Samoa	632	468
Arizona	2,041	878
Arkansas	2,330	878
California	15,385	5,460
Colorado	1,836	878
Connecticut	2,116	878
Delaware	1,185	878
District of Columbia	1,185	878
Florida	7,435	2,641
Georgia	4,951	1,757
Guam	632	468
Hawaii	1,185	878
Idaho	1,185	878
Illinois	8,050	2,857
Indiana	4,577	1,625
Iowa	2,411	905
Kansas	1,756	878
Kentucky	3,793	1,345
Louisiana	3,794	1,346
Maine	1,185	878
Maryland	2,880	1,023
Massachusetts	4,290	1,522
Michigan	7,252	2,573
Minnesota	3,136	1,113
Mississippi	2,831	1,005
Missouri	4,204	1,492
Montana	1,185	878
Nebraska	1,275	878
Nevada	1,185	878
New Hampshire	1,185	878
New Jersey	5,039	1,788
New Mexico	1,236	878
New York	13,448	4,770
North Carolina	5,709	2,026
North Dakota	1,185	878
Northern Mariana Islands	632	468
Ohio	8,809	3,126
Oklahoma	2,439	878
Oregon	1,973	878
Pennsylvania	9,951	3,530
Puerto Rico	6,636	2,355
Rhode Island	1,185	878
South Carolina	3,152	1,119
South Dakota	1,185	878
Tennessee	4,479	1,590
Texas	10,663	3,787
Trust Territory	-o-	-o-
Utah	1,387	878
Vermont	1,185	878
Virginia	4,251	1,509
Virgin Islands	632	468
Washington	2,842	1,026
West Virginia	2,284	948
Wisconsin	3,897	1,383
Wyoming	1,185	878

[Docket No. 81D-0309]

Anti-Infective Bovine Mastitis Product Development; Availability of Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guideline entitled "Guideline for Anti-Infective Bovine Mastitis Product Development" prepared by FDA's Center for Veterinary Medicine (CVM). The guideline describes the type of data required to establish target animal safety and effectiveness of anti-infective drugs used for treatment and control of infectious bovine mastitis. This guideline is a revision of a 1981 draft guideline entitled "Antimicrobial Drugs for Intramammary Infusion" which described such required data. The agency is issuing the revised guideline under a different title to be consistent with current terminology.

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This notice of availability is issued under 21 CFR 10.90(b), which provides for use of guidelines to establish procedures of general applicability that are not legal requirements but are acceptable to the agency. Sponsors may rely upon a guideline with the assurance that it represents procedures acceptable to the agency (see 21 CFR 10.90). If a sponsor believes that alternative procedures are also applicable, a guideline does not preclude a sponsor from pursuing the alternative procedures. Under such circumstances, however, the agency encourages sponsors to discuss the alternative procedures in advance with FDA to prevent the expenditure of money and effort for work that may later be found unacceptable.

Interested persons may, at any time, submit additional written comments on the guideline to the Dockets Management Branch. Such comments will be considered in determining if further revisions of the guideline are required. Respondents should submit two copies (except that individuals may submit single copies) identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch from 9 a.m. to 4 p.m., Monday through Friday.

Dated: July 11, 1985.

Marvin H. Shumate,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-17020 Filed 7-17-85; 8:45 am]

BILLING CODE 4160-01-M

Captan With Benzocaine (Holiday® Itch Aid and VIP® Mercaptol); Withdrawal of Approval of NADA

Correction

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BILLING CODE 1505-01-M

Office of Human Development Services

Intent To Reallot Basic Support and Protection and Advocacy Funds to States for Developmental Disabilities Expenditures

AGENCY: Administration on Developmental Disabilities, Office of Human Development Services, HHS.

ACTION: Notice of intent to reallot funds.

SUMMARY: The Administration on Developmental Disabilities herein gives notice of intent to reallot funds which will not be used by the Trust Territories of the Pacific and any other States prior to September 30, 1985, in accordance with section 125(d) of the Developmental Disabilities Assistance and Bill of Rights Act of 1984, Pub. L. 98-527. To be considered for receipt of additional funds under this reallotment, each State must provide the following information in writing:

(1) The amount of funds that will not be obligated prior to September 30, 1985, under its approved State Plan. If all funds will be obligated, provide a statement to that effect;

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(3) A statement that no additional funds are needed.

The information provided will be used to calculate the amounts to be reallotted and this information should be submitted no later than (30 days from date of publication) to: Betty J. Mobley, Grants and Contracts Management Division, Office of Human Development Services, Department of Health and Human Services, 200 Independence

Avenue SW., Room 341F.4 HHH Bldg., Washington, D.C. 20201.

If a State fails to provide written notice as indicated above by August 19, 1985, that State will not receive additional funds under the fiscal year 1985 reallocation of funds.

FOR FURTHER INFORMATION CONTACT: Bettye J. Mobley, (202) 245-7220.

(Catalog of Federal Domestic Assistance Program No. 13-630 Developmental Disabilities-Basic Support and Advocacy Grants)

Dated: July 11, 1985.

Jean K. Elder,

Commissioner, Administration on Developmental Disabilities.

Approved: July 15, 1985.

[FR Doc. 85-17094 Filed 7-17-85; 8:45 am]

BILLING CODE 4130-01-M

National Institutes of Health

Developmental Therapeutics Contracts Review Committee; Cancellation of Meeting

Notice of the meeting of the Developmental Therapeutics Contracts Review Committee, National Cancer Institute, National Institutes of Health, July 26, 1985, published in the Federal Register, (50 FR 25629) is hereby cancelled as fewer applications were received than expected. Therefore, it will be possible to review all applications within the time frame of the July 29-30 meeting. For further information, please contact Dr. Kendall G. Powers, Executive Secretary, National Cancer Institute, Westwood Building, Room 805, National Institutes of Health, Bethesda, Maryland 20205 (301/496-7575).

Dated: July 10, 1985.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 85-17035 Filed 7-17-85; 8:45 am]

BILLING CODE 4140-01-M

Commercial/Industrial Activities Review Schedule

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice of Review Schedule.

SUMMARY: This notice identifies a cost comparison study for a commercial/industrial activity by the National Institutes of Health during Fiscal Year 1986. This study will be in accordance with Office of Management and Budget Circular A-76.

FOR FURTHER INFORMATION CONTACT: Ana Kennedy, Division of Management Policy, National Institutes of Health, Building 31, Room 3B19, 9000 Rockville Pike, Bethesda, Maryland 20205, (301) 496-2461.

SUPPLEMENTARY INFORMATION: In accordance with OMB Circular A-76, a cost comparison is scheduled for the elevator maintenance and related services to be completed by January 1986. This activity includes administration, maintenance, repair, inspections and emergency service work for elevators, escalators, dumbwaiters, automatic doors, window washing scaffolds and automated materiel handling systems.

The activity is located at the National Institutes of Health, Bethesda, Maryland.

Dated: July 9, 1985.

James B. Wyngaarden,

Director, National Institutes of Health.

[FR Doc. 85-17033 Filed 7-17-85; 8:45 am]

BILLING CODE 4140-01-M

Public Health Service

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Toxicology and carcinogenesis studies of Telone II® were conducted by administering the commercial-grade forumlation in corn oil by gavage to groups of 52 male and 52 female F334/N rats at does of 0, 25, or 50 mg/kg and to groups of 50 male and 50 female B6C3F$_1$ mice at doses of 0, 50, or 100 mg/kg. Doses were administered three times per week for 104 weeks. Ancillary studies were conducted in which dose groups containing five male and five female rats were killed after Telone II® for 9, 18, 21, 24, or 27 months.

Under the conditions of these gavage studies, there was *clear evidence of carcinogenicity* for male F344/M rats, as indicated by Telone II®-related increased incidence of squamous cell papillomas and caricinomas of the forestomach, as well as an increased incidence of neoplastic nodules of the liver. In femal F334/N rats, there was *some evidence of carcinogenicity* because Telone II® caused an increased incidence of squamous cell papillomas of the forestomach. The experiment in male B6C3F$_1$ mice was considered to be an *inadequate study of carcinogenicity* because of reduced survival in the vehicle control group. However, there was some indication in the male mice of Telone II®-related increases of transitional cell carcinomas of the urinary bladder, squamous cell papillomas of the forestomach, and alveolar/bronchiolar adenomas and carcinomas of the lung. There was *clear evidence of carcinogenicity* for female B6C3F$_1$ mice, since Telone II® caused increased incidences of transitional cell carcinomas of the urinary bladder; Telone II® also increased the incidences of alveolar/bronchiolar adenomas of the lung and of squamous cell papillomas or carcinomas of the forestomach in the female mice. Telone II®-related non-neoplastic lesions included basal cell or hyperplasia in the forestomach of male and femal rats and male and female mice and epithelial hyperplasia of the urinary bladder in male and famale mice.

Copies of *Toxicology and Carcinogenesis Studies of Telone II®* in F344/N Rats and B6C3F$_1$ *Mice (Gavage Studies)* (*T.R. 269*) are available without charge from the NTP Public Information Office, M.D. B2-04, P.O. Box 12233, Research Triangle Park, NC, 27709. Telephone (919) 541-3991, FTS: 629-3991.

Dated: July 10, 1985.

David P. Rall,

Director.

[FR Doc. 85-17034 Filed 7-17-85; 8:45 am]

BILLING CODE 4101-01-M

Privacy Act of 1974; System of Records

AGENCY: Department of Health and Human Services, (PHS); Public Health Service, (PHS).

ACTION: Notification of establishment of a new Privacy Act system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Office of the Assistant Secretary for Health (OASH) is publishing notice of a proposal to establish a new Privacy Act system of records 09-37-0017, "Proceedings of the Board for Correction of Public Health Service Commissioned Corps Records, HHS/OASH/OM." This system, which has been a subsystem under another system of records, will continue to be used to review and act on requests to correct alleged errors or