

contamination of tissue during processing.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written or electronic comments on the guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation" dated March 2002. The document is intended to remind all tissue establishments that the current requirement to prepare, validate, and follow procedures to prevent infectious disease contamination or cross-contamination during the processing of human tissues intended for transplantation (21 CFR 1270.31(d)) includes such infectious disease agents as viruses, bacteria, fungi, and will include TSE-associated prions as technology progresses. Current regulations for human tissue intended for transplantation are found in 21 CFR parts 1270 and 1271.

This guidance is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on the validation of procedures for processing of human tissues intended for transplantation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be

used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The agency is soliciting public comment, but is implementing this guidance document immediately because of the public health concerns related to the possible risk of infectious disease contamination or cross-contamination during tissue processing. In particular, FDA's concern is heightened by recent reports from the Centers for Disease Control and Prevention about bacterial contamination of musculoskeletal allografts associated with injury as well as death in recipients of these tissues [MMWR; 50(46): 1035-1036, November 23, 2001; 50(48): 1080-1083, December 7, 2001.] FDA is requesting that you submit with your comments any information on specific methods currently used by tissue establishments to prevent infectious disease contamination and cross-contamination of tissue during processing. FDA plans to have further public discussion on this issue and to develop additional guidance containing more specific recommendations on validation methods for tissues in the future.

Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 4, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-5963 Filed 3-12-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: October 2001

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of October 2001, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
ABRANTE, HECTOR HIALEAH, FL	02/20/2002
ADAMS, BILLY WAYNE FEDERAL WAY, WA	02/20/2002
BINA, SHOKROLLAH LOS ANGELES, CA	02/20/2002
CARING RESPIRATORY SVCS, INC CORAL GABLES, FL	09/17/2001
CARROLL, MAXIE G TALLAHASSEE, FL	02/20/2002
CORVO, RENE JESSUP, GA	02/20/2002
DJGLYAN, ARUTYUN ELOY, AZ	02/20/2002
DOUGHERTY, TERENCE W CLAYTON, MO	02/20/2002
ENRIQUEZ, HONORIA MIAMI, FL	02/20/2002
ESPINOZA, THELMA AUXILIADOR SOUTHGATE, CA	02/20/2002
FAULKNER, THERESA ANN ... PHOENIX, AZ	02/20/2002
FRENZI, MICHELLE L AURORA, CO	02/20/2002
FULLER, ALISHA ANN SPRINGFIELD, OR	02/20/2002
HING, VAN DAN	02/20/2002

Subject, city, state	Effective date	Subject, city, state	Effective date	Subject, city, state	Effective date
DES MOINES, IA		LITTLETON, CO		CLARKSVILLE, AR	
HACHMEISTER, SUZANNE		MORSE, TERRY FURR	02/20/2002	VEJRASKA, EUGENE	02/20/2002
PEARL	02/20/2002	WEXFORD, PA		ALLIANCE, NE	
WONDER LAKE, IL		MUNCAN, PETAR	02/20/2002	VISSER, SUSAN C	02/20/2002
HADLICH, ELIZABETH MAY ...	02/20/2002	HOWARD BEACH, NY		KNOXVILLE, IA	
ST PAUL, MN		NEMAZEE, MAHMOUD	02/20/2002	VISSER, MELINDA JAYNE	02/20/2002
HARLAN, CAROLYN L	02/20/2002	SANTA MONICA, CA		SUSANVILLE, CA	
INDIANAPOLIS, IN		NESTOR, TIA M	02/20/2002	WAHL, REBECCA	02/20/2002
HARTLEY, LAUREL SUTCH ...	02/20/2002	HAY SPRINGS, NE		WESTERN, NE	
RICHEYVILLE, PA		NIMMO, ZWANNAH G	02/20/2002	WAHLERS, KATHLEEN A	02/20/2002
HASSER, CARRIE MARIE	02/20/2002	PAWTUCKET, RI		MUNCIE, IN	
MORA, MN		NOVICK, HOWARD ALAN	02/20/2002	WARRICK, LYNETTE ANN	02/20/2002
HASTAD, PATRICIA KAY	02/20/2002	BREINIGSVILLE, PA		ST CLOUD, MN	
BROOKLYN PARK, MN		O'BRIEN, DANIEL PATRICK ...	02/20/2002	WATKINS, DEBORAH ANN	02/20/2002
HICKMAN, DEWAYNE KEITH		LEXINGTON, KY		WINCHESTER, IL	
ANAHEIM, CA		PATTY, KENNETH D	02/20/2002	WAYNE, SYLVIA	02/20/2002
HILBURN, CHERYL LYNN	02/20/2002	BLAIRS, VA		SUN CITY WEST, AZ	
WILMINGTON, NC		PETERSON, CHERYL RENEE		WELCH, WENDY J	02/20/2002
HILL, CANDY RENEE	02/20/2002	BLOOMINGTON, MN		DECORAH, IA	
BIRMINGHAM, AL		PIER, LARRY VAUGHN	02/20/2002	WESTMORELAND, MERE-	
HYRY, PHILLIP WADE	02/20/2002	PAYSON, AZ		DITH H	02/20/2002
ISHPEMING, MI		PLANT-MAU, MARY J	02/20/2002	COLUMBIA, TN	
ILOUNO, GEORGE		CORPUS CHRISTI, TX		WILLIAMSON, CHRIS E	02/20/2002
ORANYELU	02/20/2002	POLLARD, WILLIAM W	02/20/2002	CAMP VERDE, AZ	
HARBOR CITY, CA		CORVALLIS, OR		WILSON, CAMILLE SUE	02/20/2002
IORDAMOVA, ZOYA	02/20/2002	PORTER, COLETTE S		PENDLETON, OR	
N HOLLYWOOD, CA		THREATS	02/20/2002	WOOLDRIDGE, DOUGLAS W	02/20/2002
JOHNSON, KATHLEEN RUTH		NORFOLK, VA		WELLESLEY, MA	
MINNEAPOLIS, MN		PRADO, ANGEL	02/20/2002	WRIGHT, PAMELA JEAN	02/20/2002
JONES, LUCRETIA ANN	02/20/2002	MANHASSET, NY		ROCHESTER, MN	
SALT LAKE CITY, UT		PROCTOR, ROSALIND G	02/20/2002	ZEMAN, LAURA MARIE	02/20/2002
KAPOOR, QUDRAT S	02/20/2002	PHOENIX, AZ		KETCHIKAN, AK	
ROSWELL, NM		RANTALA, MARILYN JEAN	02/20/2002		
KEESE, DIANE LYN	02/20/2002	SPRINGFIELD, IL			
CHICAGO, IL		RAY, FRANCES F	02/20/2002		
KELSEY, MARIANNE BREIER		DENVER, CO			
HIGH POINT, NC		RICHARDS, KAY ANN	02/20/2002		
KIM, BYUNG CHANG	02/20/2002	PHOENIX, AZ			
DIAMOND BAR, CA		RYAN, GERALDINE	02/20/2002		
KOENIG, NANCY LOUISE	02/20/2002	BRICK, NJ			
ROCHESTER, MN		SAMOY, GREGORIO DALUZ ..	02/20/2002		
KUSHMER, JOHN V	02/20/2002	TUCSON, AZ			
TAMPA, FL		SANDOVAL, MANUEL A	02/20/2002		
LANDPHAIR, GREGORY R	02/20/2002	NEW BRITAIN, CT			
STRYKERSVILLE, NY		SARRACCO, LORI ANN	02/20/2002		
LARA, FRANK J	02/20/2002	HAM LAKE, MN			
MESA, AZ		SCHLEIF, NANCY ANN	02/20/2002		
LAWSON, ALAN R	02/20/2002	PLYMOUTH, MN			
FAYETTEVILLE, AR		SCHULTE, CYNTHIA L	02/20/2002		
LEADER, WILLIAM O	02/20/2002	KINGMAN, AZ			
LOS ANGELES, CA		SKORA, ALAN P	02/20/2002		
LEHNERTZ, LINDA LEE	02/20/2002	DEWITT, IA			
OWATONNA, MN		SMITH, VEE LANDIS	02/20/2002		
LEVY, KENNETH D II	02/20/2002	MINNEAPOLIS, MN			
WINDSOR, CT		SOLOMON, ABRAHAM	02/20/2002		
LONNES, DEBORAH JOY	02/20/2002	LONG ISLAND CITY, NY			
ST PAUL, MN		STRUWVE, SUSAN LOUISE ...	02/20/2002		
LOOP, JERRY R	02/20/2002	RAMSEY, MN			
GRAND ISLAND, NE		STULL, AARON MYLES	02/20/2002		
LYONS, DANA	02/20/2002	ROCHESTER, MN			
ROEBLING, NJ		TAMAYO, RICKY M	02/20/2002		
MCAULEY, DONALD	02/20/2002	EL CENTRO, CA			
PHOENIX, AZ		TAYLOR, CORA REBECCA ...	02/20/2002		
MCCANN, JON SCOTT	02/20/2002	TUCSON, AZ			
RED OAK, OK		THORNTON, JUDY LYNN	02/20/2002		
MCGEE, VICKIE W	02/20/2002	EL CAJON, CA			
LA FAYETTE, GA		TOTH, JEANINE MICHELLE ...	02/20/2002		
MCGEE, ELIZABETH	02/20/2002	HONOLULU, HI			
WAYNE, NJ		TULLY, ANN MENDELSON	02/20/2002		
MILLER, LORI E	02/20/2002	DOYLESTOWN, PA			
ALLEN, TX		TUTT, KEITH E	02/20/2002		
MOONEY, SHARON RENE	02/20/2002	PROVIDENCE, RI			
FRANKVILLE, AL		UNDERWOOD, CLYDE HAM-			
MORLEY, KIMBERLY LYNNE	02/20/2002	ILTON	02/20/2002		
				FEDERAL/STATE EXCLUSION/ SUSPENSION	
				KATZAP, IZEA	02/20/2002
				JAMAICA, NY	
				MCCASKILL, EDDIE	02/20/2002
				ST LOUIS, MO	
				SAUL, STEPHEN	02/20/2002
				MARGATE, NJ	
				FRAUD/KICKBACKS	
				AMEX II	10/09/2001
				PHOENIX, AZ	
				SPRIGGS, ROBERT ALAN	11/24/2000
				FAIRFIELD, CA	
				OWNED/CONTROLLED BY CONVICTED ENTITIES	
				ADVANCED HEALTH CLINIC	02/20/2002
				MESA, AZ	
				CHILD & ADOLESCENT IN-	
				STITUTE	02/20/2002
				BEACHWOOD, OH	
				CHIROPRACTIC PLUS	02/20/2002
				LONGVIEW, TX	
				CREATIVE CARE ENLIGHT-	
				ENED	02/20/2002
				FT MYERS, FL	
				M & G HEALTH CARE, INC	02/20/2002
				MIAMI, FL	
				MAIN STREET DENTAL AS-	
				SOCIATES	12/18/2001
				FARMINGTON, CT	
				MICHAEL B AUSTIN, D O, P A	02/20/2002
				TAMPA, FL	
				PSYCHIATRIC PROFES-	
				SIONAL GROUP	02/20/2002

Subject, city, state	Effective date	Subject, city, state	Effective date	Subject, city, state	Effective date
N OLMSTED, OH		OMAHA, NE		OCONOMOWOL, WI	
DEFAULT ON HEAL LOAN		MONICA, JULIANNE H	02/20/2002		
ALEXANDER, MICHAEL A	02/20/2002	SPRING LAKE, NJ		Dated: March 4, 2002.	
ALQUIPPA, PA		NEWELL, DAVID CLIFFORD ...	02/20/2002	Calvin Anderson, Jr.,	
ARGUEDAS, WALTER G	02/20/2002	FORT BRAGG, CA		<i>Director, Health Care Administrative</i>	
HIALEAH, FL		OWGZAREK, KEITH VINCENT	02/20/2002	<i>Sanctions, Office of Inspector General.</i>	
BELLER, BRYAN D	02/20/2002	MARYSVILLE, WA		[FR Doc. 02-5944 Filed 3-12-02; 8:45 am]	
SOUTHGATE, MI		PATT, RICHARD H	02/20/2002	BILLING CODE 4150-04-P	
CAFAGNA, MARK WILLIAM		NEW YORK, NY			
SR	02/20/2002	PEISS, STUART	02/20/2002		
WEST HILLS, CA		HOFFMAN ESTATES, IL			
CAGLE, LARRY S	02/20/2002	PHILLIPS, THADDEUS		DEPARTMENT OF HEALTH AND	
AHOSKIE, NC		HILLARD III	02/20/2002	HUMAN SERVICES	
CARR, GUY A	02/20/2002	SAN ANTONIO, TX		National Institutes of Health	
HUTCHINSON, KS		PORTNOW, ROBERT THOMAS	02/20/2002		
CONSTANTINESCU, SERBAN		AS		Proposed Collection; Comment	
CRISTIA	02/20/2002	CLEVELAND, OH		Request; Policies of Academic	
PHILADELPHIA, PA		RAMU, NALAYA	02/20/2002	Institutions Regarding Tobacco	
COOPER, SHIRLEY T	02/20/2002	LOS ANGELES, CA		Industry Research Funding	
LANSDALE, PA		RASHTI, KOUROS	02/20/2002	SUMMARY: In compliance with the	
CRAIG, BRADLEY D	02/20/2002	TARZANA, CA		requirement of Section 3506(c)(2)(A) of	
SNOWFLAKE, AZ		RICHBERG, MARK H	02/20/2002	the Paperwork Reduction Act of 1995,	
DE JESUS-MIRANDA, LUIS A		PHILADELPHIA, PA		for opportunity for public comment on	
SAN JUAN, PR		RIGNEY, MARK EDWARD	02/20/2002	proposed data collection projects, the	
DIENER, ROBERT B	02/20/2002	OKLAHOMA CITY, OK		national Cancer Institute (NCI), the	
AUBURNDALE, MA		ROMERO, JOHN JOSEPH	02/20/2002	National Institutes of Health (NIH) will	
DONELSON, RICHARD BAR-		ALBURQUERQUE, NM		publish periodic summaries of proposed	
TON	02/20/2002	RORRER, MARK TIMOTHY ...	02/20/2002	projects to be submitted to the Office of	
PHOENIX, AZ		CLAYTON, OH		Management and Budget (OMB) for	
EATON, GARY D	02/20/2002	ROZENBERG, RONALD L	02/20/2002	review and approval.	
SPRINGFIELD, MO		LEVITTOWN, NY		Proposed Collection	
ELLZEY, PAUL D	02/20/2002	RUSSELL, BILL	02/20/2002	<i>Title:</i> Policies of Academic	
PRATTVILLE, AL		ST LOUIS, MO		Institutions Regarding Tobacco Industry	
FISHBOUGH, ROSS E	02/20/2002	SAID, SAED M	12/18/2001	Research Funding.	
BENSLAEM, PA		DUNIONVILLE, CT		<i>Type of Information Collection</i>	
FLOYD, THOMAS PARKER ...	02/20/2002	SANDOR, GEORGE JOSEPH	02/20/2002	<i>Request:</i> NEW.	
TRUFANT, MI		NEW YORK, NY		<i>Need and Use of Information</i>	
GREETHONG, KITIMAN	02/20/2002	SAUTMAN, SATPAL K	02/20/2002	<i>Collection:</i> This study will assess	
IRVINE, CA		PLANTATION, FL		current administrative policies of	
HAGEN, CALVIN P	02/20/2002	SCHWARTZ, FRANCIS XA-		medical schools and schools of public	
KANSAS CITY, MO		VIER JR	02/20/2002	health regarding faculty acceptance of	
HANSEN, KRIS T	02/20/2002	OAKLAND, CA		research funding from tobacco	
ST GEORGE, UT		SCHWARZ-MANDRACCHIA,		manufacturers and trade organizations.	
HORNIG-ROHAN, JAMES ED-		DENISE MA	02/20/2002	The primary objectives of the study are	
WARD	02/20/2002	WINTERSET, IA		to assess how many institutions have a	
SENECA, SC		SLOTNICK, ROBIN T	02/20/2002	tobacco-specific research funding	
IBRIK, AMIR	02/20/2002	CLEVELAND, OH		policy, their reasons for adopting or not	
SYRACUSE, NY		STOCK, ANN M	02/20/2002	adopting such a policy, and what the	
KALMAN, BETSY S	02/20/2002	BELLEVILLE, IL		requirements of those policies are. The	
RICHMOND HILL, NY		THOMPSON, JANETTE A	02/20/2002	finding will provide valuable	
KRUGMAN, LINDA L	02/20/2002	SILVER SPRING, MD		information concerning: (1) How	
LEXINGTON, KY		TOLIVER, EDWARD C	02/20/2002	academic institutions have responded to	
LE SAGE, SAHARA ADAMS ...	02/20/2002	CHICAGO, IL		concerns about researchers' funding	
LEAGUE CITY, TX		VESTICH, GEORGE T	02/20/2002	relationships in tobacco research, (2)	
LEONELLI, DAVID ROMAN SR		RICHMOND, OH		administrators' attitudes towards	
LOS ANGELES, CA		VILLANO, GUY JOHN	02/20/2002	research funding policies targeted at	
LEWIS, STEVEN R	02/20/2002	NISKAYUNA, NY		tobacco specifically; and (3) what types	
IRVING, TX		WALCHER, KEVIN RAY	02/20/2002	of requirements have been imposed on	
LINSTEADT, ELIZABETH M ...	02/20/2002	BOOKER, TX		academic researchers regarding tobacco	
DENISON, TX		WALTERS, BRIAN D JR	02/20/2002	funding.	
LUCEY, TIMOTHY D	02/20/2002	SEATTLE, WA		<i>Frequency of Response:</i> Once.	
NEWBURGH, NY		WAN, JAMES Y	02/20/2002	<i>Affected Public:</i> Individuals;	
MARTINEZ, DANIEL A	02/20/2002	MOBILE, AL		academic institutions.	
REDLANDS, CA		WHEDBEE, JOSEPH IRE-		<i>Type of Respondents:</i> academic	
MASSAKOWSKI, EDWARD A		LAND	02/20/2002	administrators.	
BENSALEM, PA		REDLANDS, CA			
MCGHEE, STEPHANIE Y	02/20/2002	WILLIAMS, ERIC A	02/20/2002		
HOUSTON, TX		TOWSON, MD			
MCINNES, THOMAS K	02/20/2002	WILSON, RONALD E	02/20/2002		
POOLESVILLE, MD		DETROIT, MI			
MEINHOLD, STEVEN DALE ...	02/20/2002	YODER, KYLE JAY	02/20/2002		
		REDWOOD CITY, CA			
		ZIMMERMAN, MARY L P	02/20/2002		