

recent literature there has been a discussion of an entity referred to as MCI. While MCI is considered by some to be a distinct clinical entity, others consider that the majority of patients diagnosed with MCI have an early form of Alzheimer's Disease. It is critical for regulatory purposes that the issues surrounding this diagnosis are fully explored. Toward that end the committee will listen to speakers and discuss the following and other related questions:

1. Can MCI be clearly defined in a clinical setting?
2. Are there valid criteria for the diagnosis of MCI?
3. Can MCI be distinguished from Alzheimer's Disease and other causes of dementia?
4. What outcome measures are appropriate to use in clinical drug trials conducted in MCI?
5. Should clinical drug trials in MCI incorporate any special features in their design?

On March 14, 2001, the committee will discuss drug development for individuals with vascular dementia. While vascular dementia is considered by some to be a distinct entity others do not agree that it can be easily distinguished from Alzheimer's Disease and/or other dementias. It is critical for regulatory purposes that the issues surrounding this diagnosis are fully explored. Toward that end the committee will listen to presentations and then discuss the following and other related questions:

1. Can vascular dementia be clearly defined in a clinical setting?
2. Are there valid criteria for the diagnosis of vascular dementia?
3. Can vascular dementia be distinguished from Alzheimer's Disease and other causes of dementia?
4. What outcome measures are appropriate to use in clinical drug trials conducted in vascular dementia?
5. Should clinical drug trials in vascular dementia incorporate any special features in their design?

FDA will provide a background position paper on MCI and on vascular dementia prior to each meeting. When the background material becomes available, it will be posted under the Peripheral and Central Nervous Systems Drugs Advisory Committee Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2001 and scroll down to the Peripheral and Central Nervous Systems Drugs meetings.)

On March 15, 2001, the committee will consider the safety and efficacy of

new drug application (NDA) 21-196, Xyrem® (sodium oxybate, Orphan Medical, Inc.), proposed to reduce the incidence of cataplexy and to improve the symptom of daytime sleepiness for persons with narcolepsy. A main focus of the deliberations will be on risk management issues.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 1, 2001. On March 13 and 14, 2001, oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. On March 15, 2001, oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. Those desiring to make formal oral presentations should notify the contact person before March 1, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 6, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

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BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: January 2001

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of January 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	
AHMED, ASHFAQ BROWNSTOWN TWP, MI	02/20/2001
BIAGGI, BART SAN JOSE, CA	02/20/2001
BINDER, MARK ALBERT UTICA, NY	02/20/2001
BISLAMIAN, ARTHUR SAMVEL LOS ANGELES, CA	02/20/2001
BODISON, LARRY L WALTERBORO, SC	02/20/2001
CENTRAL AMBULANCE SERVICE, INC CORAOPOLIS, PA	02/20/2001
CHIN, JENNY LONG BEACH, CA	02/20/2001
CRAWFORD, CAROLYN PICKENS, MS	02/20/2001
D'AMATO, JAMES W BABYLON, NY	02/20/2001
DONNELLY, BARBARA J CINCINNATI, OH	02/20/2001
ELLENWOOD, JANET L NAVARRA, OH	02/20/2001
FELEKIAN, HRACH LONG BEACH, CA	02/20/2001
GALIANO, JORGE MIAMI, FL	02/20/2001
GOLDSTEIN, JOSEPH SCARSDALE, NY	02/20/2001
GOROSH, RICHARD P LANSING, MI	02/20/2001
GREATHOUSE, BETTY LARVED, KS	02/20/2001
GUIDOTTI-ALEXANDER, ELAINE SAN JOSE, CA	02/20/2001
IMPERIAL, NORMAN ANAHEIM, CA	02/20/2001
JOHNSON, DEROTT STURTEVANT, WI	02/20/2001
JOYNER, MELBA J WINTERVILLE, NC	02/20/2001
KURINETS, VLADIMIR BROOKLYN, NY	02/20/2001
LORENZO, LORENZO HIALEAH, FL	02/20/2001
MACDONALD, DANESSA MAICHELE PUNXSUTAWNEY, PA	02/20/2001
MATHIS, NELSON D HENDERSONVILLE, NC	02/20/2001
MATO, AMPARO HIALEAH, FL	02/20/2001
MATO, ADOLFO HIALEAH, FL	02/20/2001
NICKOLAOU, MARK LOUIS SAINT JOHN, IN	02/20/2001
NIKOGOSYAN, VARDAN LOS ANGELES, CA	02/20/2001
PATEL, NIRANJAN LOS ANGELES, CA	02/20/2001

Subject city, state	Effective date	Subject city, state	Effective date	Subject city, state	Effective date
BAYSIDE, NY		SHAMOKIN, PA		CANTON, MS	
PHILLIPS, MITCHEL EARL	02/20/2001	FISHER, DAVID MICHAEL	02/20/2001	WILLIAMS, QUINNESS B	02/20/2001
LAS VEGAS, NV		SHAMOKIN, PA		NEW ORLEANS, LA	
PHILLIPS, RAMONA DENISE	02/20/2001	HARDING, VALERIE L	02/20/2001	WINFORD, MARY	02/20/2001
OKLAHOMA CITY, OK		LINWOOD, MA		COLUMBUS, MS	
PIKESH, KEVIN D	02/20/2001	HENSON, RHEA E	02/20/2001	WINTERS, DOROTHY	02/20/2001
SPRINGFIELD, IL		FAIRFAX, VA		JACKSON, MS	
PISANI, LOUIS A	02/20/2001	HYLINSKI, JOSEPH	02/20/2001	CONTROLLED SUBSTANCE CONVICTIONS	
GARDEN CITY, NY		KING OF PRUSSIA, PA		NELKIE, KAREN ANN	02/20/2001
RESTORATION COUNSELING		LEE, KIMBERLY A	02/20/2001	EAST TAWAS, MI	
CTR, INC	02/20/2001	HIGH POINT, NC		PATEL, DINKAR N	02/20/2001
SAINT JOHN, IN		MAGUIRE, SEAN M	02/20/2001	GRUNDY, VA	
RICHARDS, AARON D	02/20/2001	CINCINNATI, OH		LICENSE REVOCATION/SUSPENSION/ SURRENDERED	
DEAL, NJ		MAY, DARLA MARIE	02/20/2001	AGEE, LAWRENCE CARTER	02/20/2001
ROBLES, MARCELINO	02/20/2001	PEARL, MS		AUBURN, CA	
PHILADELPHIA, PA		MAYNARD, PAMELA P		ALDER, DAMIAN M	02/20/2001
SANVITO, ANTHONY J	02/20/2001	CARVER	02/20/2001	GULFPORT, MS	
CORAOPOLIS, PA		SMITHVILLE, TN		ALLEN, FRANK BENTON	02/20/2001
SANVITO, MARGARET M	02/20/2001	MCLAUGHLIN, GERARD P	02/20/2001	TRINITY CENTER, CA	
PITTSBURGH, PA		E LIVERPOOL, OH		ANDERSON, MEGAN	02/20/2001
SCHILLERSTROM, HERBERT		STARE, JOHN C	02/20/2001	STRATFORD, CT	
LEE JR	10/04/2000	N OLMSTED, OH		AQUINO, LOURDES ANABEL	02/20/2001
PEORIA, AZ		WEEKS, LOIS ELIZABETH	02/20/2001	PASADENA, CA	
SENEGAL, JOAN A	02/20/2001	MARIANNA, FL		ARDEHALI, MOHAMMAD	02/20/2001
PORT ARTHUR, TX		PATIENT ABUSE/NEGLECT CONVICTIONS		NEWARK, NJ	
SHAIKH, NAZIR AHMED	02/20/2001	CONNER, DEBRA KAY	02/20/2001	ARMSTRONG, PETRICIA G ...	02/20/2001
JAMAICA ESTATES, NY		CONNELLSVILLE, PA		CAPE CORAL, FL	
SHOOSTER, CHARLES NA-		FAIR, KEITH ALFRED	02/20/2001	ARORA, VIJENDER KUMAR ...	02/20/2001
THAN	02/20/2001	CHEHALIS, WA		MINNEAPOLIS, MN	
BEVERLY HILLS, CA		FLEMING, PHYLLIS R	02/20/2001	ATWELL, BRENDA DIANE	02/20/2001
THOMAS, ANTHONY	02/20/2001	BROOKHAVEN, MS		NARROWS, VA	
BERKSHIRE, UK,		GALBRAITH, CHARLES WIL-		BAINBRIDGE, MICHELLE A ...	02/20/2001
ZEYTUNYAN, ARUTYUN	02/20/2001	LIS	02/20/2001	ERIE, PA	
VAN NUYS, CA		ENID, OK		BARRY, CHERYL JOAN	02/20/2001
FELONY CONVICTION FOR HEALTH CARE FRAUD		GBENGA, ADENIRAN B	02/20/2001	PARIS, TX	
ANGLADA, NITZA	02/20/2001	COLUMBUS, OH		BARTLETT, JENNIFER M	02/20/2001
JAMAICA, NY		GREEN, MARILYN DELORIS ..	02/20/2001	SPRINGFIELD, VT	
AUSTIN, LATOYA	02/20/2001	CLEVELAND, OH		BAURLEY, JAMES R	02/20/2001
MILWAUKEE, WI		HALL, INDIA S	02/20/2001	MARTINSVILLE, IN	
CARR, ALESHIA B	02/20/2001	PEPPER TREE VILAS, OH		BEASLEY, KAREN	02/20/2001
LEXINGTON, KY		HANDY-CLARK, VICKI	02/20/2001	JACKSON, MS	
CHAVARRIA, KEVIN	02/20/2001	JACKSON, MS		BEATTY, BRUCE E	02/20/2001
MONTGOMERY, PA		HARPER, DOROTHY	02/20/2001	MARION, IN	
GRANGER, MAI D	02/20/2001	MCCOMB, MS		BECK, ALLAN GERSON	02/20/2001
WILLINGBORO, NJ		HEBB, SONJA M	02/20/2001	WATERFORD, NJ	
HARRIS, TIFFANY ANN	02/20/2001	CASSOPOLIS, MI		BERG, ALBERT JACK	02/20/2001
MILWAUKEE, WI		HUBER, MARK D	02/20/2001	MAITLAND, FL	
JOHNSON, SHEILA RENAE	02/20/2001	BLOOMER, WI		BETOUSHANA, DEMATOUR ..	02/20/2001
MILWAUKEE, WI		JAMES, DELORIS MAT-		SAN JOSE, CA	
MERNICK, MITCHELL HAR-		THEWS	02/20/2001	BISHOP, KAREN ELIZABETH	02/20/2001
VEY	02/20/2001	MINDEN, LA		EL CAMPO, TX	
OTISVILLE, NY		JEFFERSON, BANSHEE P	02/20/2001	BLAKE, HAYDEN ANTHONY ..	02/20/2001
PETERSON, CHARMOND		MANSFIELD, OH		MEDFORD, NY	
ANTICE	02/20/2001	JOHNSON, RENEE J	02/20/2001	BOE, NAN GALLAGHER	02/20/2001
MILWAUKEE, WI		COLUMBUS, OH		TAUNTON, MA	
POWELL, VICKIE REGINA	02/20/2001	PAIGE, STACY R	02/20/2001	BOGARDUS, RICHARD	
MILWAUKEE, WI		HALLETTVILLE, TX		JAMES	02/20/2001
RAMFT, LINDA J	02/20/2001	PAYNTER, SHANNON B	02/20/2001	SACRAMENTO, CA	
WINTER PARK, FL		STANARDSVILLE, VA		BOLES, CAROL A	02/20/2001
WALDEN, GLADYS MARIE	02/20/2001	RISHEL, THOMAS	02/20/2001	BELLVIEW, FL	
HILLSBORO, AL		LONG BEACH, MS		BONANCA, PATRICIA S	02/20/2001
FELONY CONTROL SUBSTANCE CONVICTION		RUDOWSKY, LINDA	02/20/2001	FALL RIVER, MA	
ALLGOOD, LISA	02/20/2001	PARMA, OH		BOWER, KAREN	02/20/2001
GOODLETTSVILLE, TN		SIDHU, DARSHAN SINGH	02/20/2001	BERWICK, PA	
BAYME, LLOYD G	02/20/2001	SALINAS, CA		BRADEN, CLARA T	02/20/2001
LONG BRANCH, NJ		SIMMONS, JOHN H II	02/20/2001	LAKE CITY, TN	
BECKER, DAVID STEPHEN	02/20/2001	LUFKIN, TX		BRADFORD, SUSAN L	02/20/2001
HALLANDALE, FL		STRAWBERRY, MICHAEL	02/20/2001		
BURNS, JOHN EDWARD	02/20/2001	LEXINGTON, MS			
		STROUSE, STEPHANIE	02/20/2001		
		MILLERSBURG, OH			
		WILLIAMS, DEBBIE	02/20/2001		

Subject city, state	Effective date	Subject city, state	Effective date	Subject city, state	Effective date
COATSVILLE, PA		BOSTON, MA		LODI, CA	
BRADFORD, IDA J	02/20/2001	FINLEY, CYNTHIA D	02/20/2001	MANN, DONNA JEAN	02/20/2001
GOODLETTSVILLE, TN		DURAND, MI		RIVERDALE, UT	
BREEDLOVE, KIRSTEN LEE ..	02/20/2001	FLYNN, JOHN EDWARD JR ...	02/20/2001	MARQUEZ, CAMILO R	02/20/2001
SHERMAN, TX		LEVITTOWN, PA		PHOENECIA, NY	
BRELAND, PAMELA C	02/20/2001	FODIMAN, MARTIN S	02/20/2001	MARTIN, GEORGIA MARIE	02/20/2001
RIDGELAND, MS		MEMPHIS, TN		RUPERT, ID	
BROWN, MARK W	02/20/2001	FORLIZZO, JOSEPH	02/20/2001	MARTIN, LAWRENCE F	02/20/2001
ENTERPRISE, MS		ST PETERSBURG, FL		WAYNESBURG, PA	
BRUSOLA, LEONIDA BANAL ..	02/20/2001	FRASE-GONZALES, TERESA		MARTIN, ELIZABETH MUR-	
SEATTLE, WA		MARIE	02/20/2001	RAY	02/20/2001
BUCK, ROBERT ARCHIE	02/20/2001	NEW SMYRNA BEACH, FL		HOLLYWOOD, FL	
KALAMAZOO, MI		FRIEDMAN, BOBBI ANN	02/20/2001	MARTZ, BARBARA	02/20/2001
BURDETTE, VIVIAN REED	02/20/2001	SAN DIEGO, CA		MOYIE SPRINGS, ID	
SENATOBIA, MS		GAGNON, DIANN H	02/20/2001	MCGRIFF, LEISA DIANE	02/20/2001
BURGE, SHERRI ANN	02/20/2001	SPRINGFIELD, MA		HANCEVILLE, AL	
NAMPA, CA		GAMAL, DEEMA ANN	02/20/2001	MCGUINESS, JOSEPH LEWIS	02/20/2001
BURNS, PEGGY LOUISE	02/20/2001	LIVONIA, MI		PITTSBURGH, PA	
STAR CITY, AR		GARVEY, LEO WILLIAM	02/20/2001	MCINTOSH, JOE G	02/20/2001
BUTLER, JOHN JEFFRIES	02/20/2001	PARCHOUE, NY		OVETT, MS	
STOCKTON, CA		GILDER, MICHAEL O	02/20/2001	MCKERRIGAN, MONTE G	02/20/2001
CAMP, JANICE E	02/20/2001	ALLISON PARK, PA		KOKOMO, IN	
MANCHESTER, CT		GILL, LORI ANN	02/20/2001	MILLAR, WILLIAM H	02/20/2001
CAMPBELL, MARGARET		IDAHO FALLS, ID		PHILADELPHIA, PA	
JANE	02/20/2001	GREIDER, ELAINE M	02/20/2001	MITCHELL, BRENDA KAY	02/20/2001
WATERTOWN, NY		OAKVILLE, CT		MANSFIELD, TX	
CAMPBELL, FRANCIS MI-		HAMILTON, CYNTHIA JEAN ...	02/20/2001	MLYNSKI, CHARLES ED-	
CHAEI	02/20/2001	AMERICAN CANYON, CA		WARD JR	02/20/2001
SAN JOSE, CA		HANINCHECK, SUSAN	02/20/2001	WYTHEVILLE, VA	
CANDIA, TYWILLA J	02/20/2001	BALTIMORE, MD		MOHS, SHEILA GARDNER	02/20/2001
BOONEVILLE, MS		HANSON-LIZEWSKI, KATRINA	02/20/2001	VISALIA, CA	
CARNAHAN, TRACY ELIZA-		WINOOSKI, VT		NDAWULA, PAUL	02/20/2001
BETH	02/20/2001	HARRISON-EKLUND, CATH-		CERRITOS, CA	
CONNEAUT LAKE, PA		ERINE	02/20/2001	NELSON, GENEVIEVE SIGNE	
CHESHER, BEVERLY V G	02/20/2001	W HAMPTON, NY		SWENSON	02/20/2001
BUCHANAN DAM, TX		HAYNES, TERESA MAE	02/20/2001	JEROME, ID	
CHESTER, ALTHEA LORETTA		SACRAMENTO, CA		NEWSON, GERTRUDE O	02/20/2001
MORENO VALLEY, CA		HENDERSON, WILLIAM		CHICAGO, IL	
CHRISTY, ELAINE	02/20/2001	LARRY	02/20/2001	NEWTON, SUSAN E	02/20/2001
WALDORF, MD		WILDOMAR, CA		NEW CASTLE, PA	
COLINA, ERNESTO	02/20/2001	HEUSNER, JAMES J	02/20/2001	NICHOLSON, PENNY KATE ...	02/20/2001
PLANT CITY, FL		ACWORTH, GA		SAN ANSELMO, CA	
COLLIER, KELLY	02/20/2001	HILLEGAS, SHERRY	02/20/2001	O'SHEA, FRANK M	02/20/2001
ST PETERSBURG, FL		BALTIMORE, MD		ELLICOTT CITY, MD	
COLLINS, KENNETH G	02/20/2001	HILSE, ANDREA M	02/20/2001	OBERDORFER, JUDITH M	02/20/2001
COLORADO SPRINGS, CO		LAWRENCE, MA		CORONA, CA	
CONLEE, STEVEN PAUL	02/20/2001	HINES, JOHN EDWARD	02/20/2001	ODIE, ELAINE	02/20/2001
EDINBURG, TX		FULLERTON, CA		JACKSON, MS	
CUCCIA, RONALD DANIEL	02/20/2001	HOLBERT, CHARLES MIKE	02/20/2001	OLADINNI, ALLEN O	02/20/2001
SAN DIMAS, CA		VANCLEAVE, MS		LOUISVILLE, KY	
CUNNINGHAM, PATRICK JO-		INGLE, ALISON RENEE	02/20/2001	OLIVER, BONNIE L	02/20/2001
SEPH	02/20/2001	GUIN, AL		RED CREEK, NY	
CLARKSTON, WA		JACOBS, JANET KAY	02/20/2001	OMOROGBE, FLORA MAE	02/20/2001
CYR, JOSEPH GUYNEMER	02/20/2001	SAN BERNARDINO, CA		BELLWOOD, IL	
VAN BUREN, ME		JOHNSON, LINDA K	02/20/2001	PADULA, MICHAEL JOHN	02/20/2001
CZERTKO, GEORGE	02/20/2001	ST JOHNSBURY, VT		MOSCOW, ID	
WARREN, MI		KING, RHONDA CYLLE	02/20/2001	PALMER, ASHLEY D	02/20/2001
DIONEDA, RUDOLFO DUAZO		GARY, IN		LEBANON, NH	
GRANITE CITY, IL		KIRKPATRICK, CHRISTINE J		PARRISH, CHARLES EZRA	
DIXON, CATHY LYNN	02/20/2001	BRISSETTE	02/20/2001	JR	02/20/2001
JONESBORO, AR		NORTHFIELD, VT		BRODNAX, VA	
DODD, WARREN DUANE	02/20/2001	KONOBECK, MARIAN VIR-		PASCHAL, NORMA J	02/20/2001
THOUSAND OAKS, CA		GINIA	02/20/2001	CLARKSDALE, MS	
DOERING, MARY C	02/20/2001	STILLWATER, MN		PAUL, NANCY E	02/20/2001
LITHIA SPRINGS, GA		KRIEGER, KATHY FUNK	02/20/2001	FLORA, MS	
DOLPH, WILLIAM W JR	02/20/2001	CHAMBERSBURG, PA		PETTWAY, BARBARA	
HOMEWOOD, IL		KUSSE, LEE JOHN	02/20/2001	BAGGETT	02/20/2001
ECKARD, SHERIE BOWSER ..	02/20/2001	DANNEMORA, NY		MT OLIVE, MS	
MCKEES ROCKS, PA		KYLES, VANESSA	02/20/2001	PHELPS, CAROL B	02/20/2001
ELLISON, DIANE N	02/20/2001	MONROEVILLE, AL		SHEAP RANCH, CA	
LEWISTON, ID		LOMELIN, EDWARD	02/20/2001	PHOENIX, JANA KAY	02/20/2001
FERRO, JOSEPH C	02/20/2001	LAREDO, TX		CENTRALIA, IL	
ASTON, PA		MAGNUS, VERNON JOHN	02/20/2001	PLUMMER, JULIA C	02/20/2001
FIDDES, ROBERT ALAN	02/20/2001				

Dated: February 5, 2001.
Calvin Anderson, Jr.,
*Director, Health Care Administrative
Sanctions, Office of Inspector General.*
[FR Doc. 01-3681 Filed 2-13-01; 8:45 am]
BILLING CODE 4150-04-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Substance Abuse and Mental Health
Services Administration**

**Agency Information Collection
Activities: Proposed Collection;
Comment Request**

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.