Draft-Not for Implementation

Guidance for Industry [1]: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use

I. Introduction

This document pertains to commercially-produced fibrin sealants composed of purified, virus-inactivated/removed human fibrinogen and human or bovine thrombin, with or without added components such as virus-inactivated/removed human factor XIII and/or aprotinin. Such products are currently available in Europe and Canada as hemostasis agents. Although manufacturers and clinicians in the United States have been actively engaged in the development and testing of fibrin sealants, no fibrin sealant product has been licensed in this country. This document outlines the agency's current position with regard to clinical data used to support licensure of safe and effective commercially-produced fibrin sealants in the United States.

II. Background

As early as 1909, surgeons were reporting the hemostatic properties of fibrin powder used in the operative field. In the 1940s, combinations of fibrinogen and thrombin were first utilized. The development of Cohn fractionation in the 1940s, and a method for cryoprecipitation of fibrinogen in the 1960s, led to the development of fibrin sealants in the 1970s. However, fibrinogen concentrates were found to transmit hepatitis and thus all U.S. licenses for Fibrinogen (Human) were revoked on December 7, 1977. Since that time, a number of manufacturers have been evaluating a new generation of virus-inactivated/removed fibrin sealants.

In 1994, the FDA co-sponsored a conference on the characteristics and clinical uses of fibrin sealants, held at the Uniformed Services University of the Health Sciences, Bethesda, Maryland (summarized in Transfusion 35:783–790, 1995). A number of academic investigators presented data from clinical trials in which fibrin sealants either reduced blood loss or reduced the time to achieve hemostasis. However, based on the available data, FDA representatives were of the opinion that a direct clinical benefit to patients treated with fibrin sealant should be demonstrated in a well-controlled clinical trial to support product licensure for a narrow indication.

Despite FDA's requests for well-controlled trials with patient outcomes as endpoints, many clinicians have been reluctant to conduct placebo-controlled trials in settings where they view the standard of care to be the use of fibrin sealant prepared on site from commercial bovine thrombin and various sources of fibrinogen. These clinicians consider the use of locally-prepared fibrin sealant to be of such benefit in controlling bleeding in confined or nearly inaccessible areas that a placebo-controlled trial would put the control patients at significant and unnecessary risk. However, locally-prepared fibrin sealants are not standardized or consistent, and the available sources of fibrinogen are not treated to inactivate or remove viruses.

III. Guidance

Based on clinical trial experience since 1994, FDA's Center for Biologics Evaluation and Research (CBER) proposes to consider, for licensure of commercially-produced fibrin sealants, data from pivotal studies in which the primary endpoint is hemostasis effectiveness. This review standard is similar to that used by the Center for Devices and Radiological Health, in clearing a number of commercial medical devices on the basis of clinical studies in which the primary endpoint was control of hemostasis within a specific time in a variety of clinical settings. CBER proposes that time to hemostasis could also serve as a primary endpoint for pivotal studies of fibrin sealants.

As in the past, CBER also encourages manufacturers to conduct well-controlled clinical trials using a variety of other endpoints, including blood loss, transfusion requirements, tissue sealing, and wound healing. Endpoints for such trials will be reviewed on a case-by-case basis. Manufacturers who demonstrate the safety and efficacy of their fibrin sealant preparations for specific indications may, upon FDA licensure, label and promote their products for these indications. FDA licensure for a given indication will denote that the specific formulation of fibrin sealant is safe and effective for that specific indication.

For fibrin sealant products containing multiple biologic components, the contribution of each component may be demonstrated in a non-clinical setting appropriate to the indication(s) sought, although the overall efficacy of multiple-component fibrin sealant products should be demonstrated in clinical trials. Proposals to utilize in vitro and/or animal studies to support the inclusion of multiple biologic components into a fibrin sealant product should be discussed with CBER.

The following points are proposed for review of pivotal clinical trials of fibrin sealant products:

1) Fibrin sealant products should be tested in settings and under conditions where they would normally be expected to be used in clinical practice.

2) Fibrin sealant products may be tested against a placebo, a cleared hemostatic device, or other control, as appropriate.

3) Efficacy of fibrin sealant products may be tested by using either hemostasis endpoints or other measures of clinical benefit, depending on the indications sought.

IV. Comments

The agency will review all submitted comments and consider them in the preparation of any final guidance document. Two copies of any comment should be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

[FR Doc. 98–1664 Filed 1–23–98; 8:45 am]

BILLING CODE 4160–01–F

[1] This draft guidance document represents the FDA's current thinking on efficacy studies to support marketing of fibrin sealant products manufactured for commercial use. 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 requirements fo the applicable statute, regulations, or both. For additional copies of this guidance, contact the Office of Communication, Training and Manufacturers Assistance, HFM–40, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that 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. Persons with access to the INTERNET may obtain the document using the World Wide Web (WWW) by connecting to CBER at ''http//www.fda.gov/cber/guidelines.htm''.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

HCFA–2005-NC

RIN 0938–AI39

Medicaid Program; State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals: Federal Fiscal Year 1998

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with Comment Period.

SUMMARY: Section 4732 of the Balanced Budget Act of 1997 (Public Law 105–33) amended the Social Security Act to provide for two additional eligibility groups of low-income Medicare beneficiaries for whom Medicaid payment can be made for Medicare Part B premiums during the period beginning January 1998 and ending December 2002. This notice announces the Federal fiscal year 1998 State allotments that are available to pay Medicare Part B premiums for these two new eligibility groups and describes the methodology used to determine each State's allotment.

DATES: *Effective Date:* This is a major rule under 5 U.S.C. section 804(2). As indicated in the preamble of this notice, pursuant to section 5 U.S.C. section 553(b)(B), for good cause we find that prior notice and comment procedures are unnecessary and impracticable. Pursuant to 5 U.S.C. section 808(2), this notice is effective January 1, 1998, for

allotments for payment of Medicare Part B premiums for individuals in calendar year 1998 from the allocation for fiscal year 1998.

Comment Date: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 27, 1998.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2005–NC, P.O. Box 7517, Baltimore, MD 21207–0517, or

If you prefer, you may deliver your written comments (one original and three copies to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–2005–NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after the publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW, Washington DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 37194, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/su__docs/, by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512-1661; type swais, then login as guest (no password required).

FOR FURTHER INFORMATION CONTACT: Miles McDermott, (410) 786–3722

SUPPLEMENTARY INFORMATION:

I. Background

Section 1902 of the Social Security Act (the Act) sets forth the requirements for State plans for medical assistance. Prior to August 5, 1997, section 1902(a)(10)(E) of the Act specified that the State Medicaid plan must provide for Medicare cost-sharing for three eligibility groups of low-income Medicare beneficiaries. These three groups included qualified Medicare beneficiaries (QMBs), specified low-income Medicare beneficiaries (SLMBs), and qualified disabled and working individuals (QDWIs).

A QMB is an individual entitled to Medicare Part A with income at or below the Federal poverty line and resources below $4,000 for an individual and $6,000 for a couple. A SLMB is an individual who meets the QMB criteria, except that his or her income is between a State established level (at or below the Federal poverty line) and 120 percent of the Federal poverty line. A QDWI is an individual who is entitled to enroll in Medicare Part A, whose income does not exceed 200 percent of the Federal poverty line for a family of the size involved, whose resources do not exceed twice the amount allowed under the Supplementary Security Income (SSI) program, and who is not otherwise eligible for Medicaid. The definition of Medicare cost-sharing at section 1905(p)(3) of the Act includes payment for premiums for Medicare Part B.

Section 4732 of the Balanced Budget Act of 1997 (BBA), enacted on August 5, 1997, amended section 1902(a)(10)(E) of the Act to require States to provide for Medicaid payment of the Medicare Part B premiums for two additional eligibility groups of low-income Medicare beneficiaries, referred to as qualifying individuals (QIs). Specifically, a new section 1902(a)(10)(E)(iv)(I) of the Act is added, under which States must pay the full amount of the Medicare Part B premium for selected qualifying individuals who would be QMBs but for the fact that their income level is at least 120 percent but less than 135 percent of the Federal poverty line for a family of the size involved. These individuals cannot otherwise be eligible for medical assistance under the approved State Medicaid plan.

The second group of QIs, added under section 1902(a)(10)(E)(iv)(II) of the Act, includes Medicare beneficiaries who would be QMBs except that their income is between 135 percent and 175 percent of the Federal poverty line for a family of the size involved, who are not otherwise eligible for Medicaid under the approved State plan. These QIs are eligible for a portion of Medicare cost-sharing consisting only of a percentage of the increase in the Medicare Part B premium attributable to the shift of Medicare home health coverage from Part A to Part B (as provided in section 4611 of the BBA).

The BBA also added a new section 1933 to the Act to provide for Medicaid payment of Medicare Part B premiums for QIs. (The previous section 1933 is redesignated as section 1934.) Section 1933(a) specifies that a State plan must provide, through a State plan amendment, for medical assistance to pay for the cost of Medicare cost-sharing on behalf of qualifying individuals who are selected to receive assistance.

Section 1933(b) of the Act sets forth the rules that States must follow in selecting QIs and providing payment for Medicare Part B premiums. Specifically, the State must permit all qualifying individuals to apply for assistance and must select individuals on a first-come, first-served basis (that is, the State must select QIs in the order in which they apply). Under section 1933(b)(2)(B) of the Act, in selecting persons who will receive assistance in years after 1998, States must give preference to those individuals who received assistance as QIs, QMBs, SLMBs, or QDWIs in the last month of the previous year and who continue to be (or become) QIs. Under section 1933(b)(4), persons selected to receive assistance in a calendar year are entitled to receive assistance for the remainder of the year, but not beyond, as long as they continue to qualify. The fact that an individual is selected to receive assistance at any time during the year does not entitle the individual to continued assistance for any succeeding year. Because the State's allotment is limited by law, section 1933(b)(3) of the Act provides that the State must limit the number of QIs so that the amount of assistance provided during the year is approximately equal to the State's allotment for that year.

Section 1933(c) of the Act limits the total amount of Federal funds available for payment of Part B premiums each fiscal year and specifies the formula that is to be used to determine an allotment for each State from this total amount. For States that execute a State plan amendment in accordance with section 1933(a) of the Act, a total of $1.5 billion is allocated over 5 years as follows: $200 million in FY 1998; $250 million in FY 1999; $300 million in FY 2000; $350 million in FY 2001; and $400 million in FY 2002.

The Federal matching rate for Medicaid payment of Medicare Part B premiums for qualifying individuals is 100 percent for expenditures up to the amount of the State's allotment. No Federal matching funds are available for expenditures in excess of the State allotment amount. Administrative expenses associated with the payment of Medicare Part B premiums for QIs remain at the 50 percent matching level and are not part of the State's allotment.

The amount appropriated for each fiscal year is to be allocated among States according to the formula set forth in section 1933(c)(2) of the Act. The formula provides for an amount to each State that is to be based on each State's share of the Secretary's estimate of the ratio of: (1) an amount equal to the sum of (a) twice the total number of individuals who meet all but the income requirements for QMBs, whose incomes are at least 120 percent but less than 135 percent of the Federal poverty line, and who are not otherwise eligible for Medicaid, and (b) the total number of individuals in the State who meet all but the income requirements for QMBs, whose incomes are at least 135 percent but less than 175 percent of the Federal poverty line, and who are not otherwise eligible for Medicaid, to (2) the sum of all of these individuals under item (1) for all eligible States.

II. Provisions of this Notice

This notice announces the availability of individual State allotments for Federal fiscal year 1998 for the Medicaid payment of Medicare Part B premiums for qualifying individuals identified under sections 1902(a)(10)(E)(iv) (I) and (II) of the Act.

In this notice, we are not applying precisely the statutory formula to determine the individual State allotments. A precise application of the allocation formula in the statute would require us to determine State-specific estimates of the number of individuals who:

- Are entitled to Medicare Part A;
- Have incomes in the poverty level ranges specified;
- Have assets not exceeding twice the amount allowed under the SSI program; and
- Would not be eligible for Medicaid but for the provisions of section 1902(a)(10)(E) of the Act regarding QIs.

Section 4732(c)(2) of the BBA allows HCFA to take an estimate of the ration of the relevant numbers. We have not been able to locate any available current data that would permit us to directly produce the estimates specified in the statute. As an alternative to direct measurement, we believe that estimates might be derived from models of income, assets, and State Medicaid eligibility. Estimates could be constructed using available data sources; however such an approach would be very time-consuming and resource-intensive and may still not produce credible State-level estimates. Consequently, we are approximating the required estimates by using data from the U.S. Census Bureau on the number of individuals who, according to its March Current Population Survey (CPS), are Medicare beneficiaries, have incomes in the appropriate ranges, and are not enrolled in Medicaid.

In order to reduce the variability of State-level estimates derived from CPS data, we have used a moving average of the most recent 3 years of available data. For the FY 1998 allotments shown in the table below, we have averaged CPS data for the years 1994 through 1996. Specifically, the Federal fiscal year 1998 allotments have been calculated as follows:

A_T=Total amount to be allocated

$M1_i$=3-year average of the number of Medicare beneficiaries in state i who are not enrolled in Medicaid and whose incomes are at least 120 percent but less than 135 percent of Federal poverty line

$M2_i$=3-year average of the number of Medicare beneficiaries in State i who are not enrolled in Medicaid and whose incomes are at least 135 percent but less than 175 percent of Federal poverty line.

Then, the allotment reserved for State *i* is determined by the following formula:

$$A_i = \left[\frac{2 \cdot M1_i + M2_i}{\sum_j \left(2 \cdot M1_j + M2_j\right)} \right] \cdot A_T .$$

The resulting allotments are shown by State in the table below.

ESTIMATED STATE ALLOTMENTS FOR MEDICAID PAYMENTS OF MEDICARE PART B PREMIUMS

State	(a) M1[1]	(b) M2[2]	(c) [2×(a)]+(b)	State share of (c) (percent)	State FY 98 allocation (in thousands)
AK	0	2	2	0.03	$63
AL	36	65	137	2.14	4,283
AR	21	37	79	1.23	2,470
AZ	18	50	86	1.34	2,688
CA	99	311	509	7.96	15,911
CO	13	33	59	0.92	1,844
CT	13	65	91	1.42	2,845
DC	2	3	7	0.11	219
DE	4	9	17	0.27	531
FL	89	270	448	7.00	14,004
GA	42	102	186	2.91	5,814
HI	4	9	17	0.27	531
IA	15	49	79	1.23	2,470
ID	4	15	23	0.36	719
IL	75	167	317	4.95	9,909
IN	25	92	142	2.22	4,439
KS	13	41	67	1.05	2,094
KY	18	91	127	1.98	3,970
LA	27	56	110	1.72	3,439
MA	37	83	157	2.45	4,908

ESTIMATED STATE ALLOTMENTS FOR MEDICAID PAYMENTS OF MEDICARE PART B PREMIUMS—Continued

State	(a) M1[1]	(b) M2[2]	(c) [2×(a)]+(b)	State share of (c) (percent)	State FY 98 allocation (in thousands)
MD	25	72	122	1.91	3,814
ME	7	27	41	0.64	1,282
MI	44	122	210	3.28	6,565
MN	18	55	91	1.42	2,845
MO	30	81	141	2.20	4,408
MS	26	42	94	1.47	2,938
MT	8	16	32	0.50	1,000
NC	58	110	226	3.53	7,065
ND	5	11	21	0.33	656
NE	10	26	46	0.72	1,438
NH	7	17	31	0.48	969
NJ	51	118	220	3.44	6,877
NM	10	29	49	0.77	1,532
NV	7	19	33	0.52	1,032
NY	92	271	455	7.11	14,223
OH	56	167	279	4.36	8,721
OK	26	47	99	1.55	3,095
OR	22	53	97	1.52	3,032
PA	82	213	377	5.89	11,785
RI	7	18	32	0.50	1,000
SC	27	52	106	1.66	3,314
SD	5	9	19	0.30	594
TN	39	56	134	2.09	4,189
TX	78	221	377	5.89	11,785
UT	4	18	26	0.41	813
VA	19	81	119	1.86	3,720
VT	4	7	15	0.23	469
WA	9	67	85	1.33	2,657
WI	10	56	76	1.19	2,376
WV	19	39	77	1.20	2,407
WY	2	4	8	0.13	250
Total	1362	3674	6398	100.00	200,000

[1] Three-year average of number (000) of Medical beneficiaries in State who are not enrolled in Medicaid but whose incomes are at least 120 but less than 135 of Federal Poverty Line.

[2] Three-year average of number (000) of Medicare beneficiaries in State who are not enrolled in Medicaid but whose incomes are at least 135 but less than 175 of Federal Poverty Line.

III. Waiver of Advance Public Comment and 30-Day Delay in Effective Date

We ordinarily publish an advance notice in the **Federal Register** for a notice containing substantive rules to provide a period for public comment. However, we may waive that procedure if we find good cause that notice and comment are impractical, unnecessary, or contrary to the public interest. In addition, we also normally provide a delay of 30 days in the effective date. However, if adherence to this procedure would be impractical, unnecessary, or contrary to public interest, we may waive the delay in the effective date.

We are adopting this notice as a final with comment period without publication of a proposed notice because of the need to notify individual States in advance of the limitations with Federal matching funds in their Medicaid expenditures for payment of Medicare Part B premiums for qualifying individuals. Publication of a proposed notice with a 60-day comment period prior to publication of a final notice would, we believe, be contrary to the public interest. The law is specific regarding the total amount available for Medicare Part B premiums for qualifying individuals and the formula that is to be used to determine individual State allotments. Therefore, we find good cause to waive issuance of a proposed notice and to issue the notice as final.

Also, because States can begin making payments for Medicare Part B premiums for qualifying individuals as early as January 1, 1998, we are not making the effective date of the notice the usual 30 days after publication. For the reasons discussed above, we find good cause to waive the usual 30-day delay.

Although we are publishing this as a final notice, we are providing a 60-day period for public comment. Because of the large number of items of correspondence we normally receive, we are not able to acknowledge or respond to the comments individually. However, if we decide that changes are necessary as a result of our consideration of timely comments, we will issue an additional notice and respond to the comments in that notice.

IV. Effect of the Contract with America Advancement Act

Normally, under 5 U.S.C. section 801, as added by section 251 of Public Law 104–121, the effective date of a major rule is delayed 60 days for Congressional review. This has been determined to be a major rule under 5 U.S.C. section 804(2). However, as indicated in section III of this notice with comment period, we have found that good cause exists to dispense with prior notice and comment procedures since they are unnecessary and impracticable under the circumstances. Pursuant to 5 U.S.C. section 808(2), a rule shall take effect at such time as the Federal agency promulgating the rule determines if it finds, for good cause, that prior notice and comment procedures are unnecessary or impracticable. Accordingly, under the exemption provided in 5 U.S.C. section

808(2), this notice with comment period is effective January 1, 1998, for allotments for payments of Medicare Part B premiums for individuals in calendar year 1998 from the allotment for fiscal year 1998.

V. Regulatory Impact Statement

We have examined the impact of this notice with comment period as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered to be small entities.

This notice with comment period implements provisions of the Balanced Budget Act of 1997 to allocate, among the States, Federal funds to provide Medicaid payment for Medicare Part B premiums for two additional groups of low-income Medicare beneficiaries. The total amount of Federal funds available during a Federal fiscal year and the formula for determining individual State allotments are specified in the law. We have applied the statutory formula for the State allotments except for the use of specified data. Because the data specified in the law were not currently available, we have used comparable data from the U.S. Census Bureau on the number of possible qualifying individuals in the States.

We believe that the statutory provisions implemented in this notice with comment period will have a positive effect on States and individuals. Federal funding at the 100 percent matching rate is available for Medicare cost-sharing for Medicare Part B premium payments for qualifying individuals and a greater number of low-income Medicare beneficiaries will be eligible to have their Medicare Part B premiums paid under Medicaid.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined and certify that this notice with comment period will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice with comment period was reviewed by the Office of Management and Budget.

Authority: Sections 1902(a)(10), 1933 of the Social Security Act (42 U.S.C. 1396a), and Public Law 105–33.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: December 12, 1997.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: January 13, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–1675 Filed 1–23–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute on Drug Abuse (NIDA) Initial Review Group and Special Emphasis Panel meetings.

Purpose/Agenda: To review and evaluate grant applications.

Name of Committee: Neurophysiology and Neuroanatomy Research Subcommittee.

Date: February 9–11, 1998.

Time: 8:30 a.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Gamil Debbas, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–2620.

Name of Committee: Human Development Research Subcommittee.

Date: February 10, 1998.

Time: 9:00 a.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Kesinee Nimit, M.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–9042.

Name of Committee: Basic Behavioral Science Research Subcommittee.

Date: February 10–12, 1998.

Time: 8:30 a.m.

Place: Key Bridge Marriott Hotel, 1401 Lee Highway, Arlington, VA 22209.

Contact Person: Mark Swieter, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–42, Telephone (301) 443–2620.

Name of Committee: Epidemiology and Prevention Research Subcommittee.

Date: February 10–12, 1998.

Time: 8:30 a.m.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Raquel Crider, Ph.D., Scientific Review Administrator, Office Of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–9042.

Name of Committee: Molecular, Cellular and Chemical Neurobiology Research Subcommittee.

Date: February 10–12, 1998.

Time: 8:30 a.m.

Place: Ritz-Carlton Hotel at Pentagon City, 250 South Hayes Street, Arlington, VA 22202.

Contact Person: Rita Liu, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–9042.

Name of Committee: NIDA Special Emphasis Panel (Molecular, Cellular and Chemical Neurobiology).

Date: February 12, 1998.

Time: 9:00 a.m.

Place: Ritz-Carlton Hotel at Pentagon City, 250 South Hayes Street, Arlington, VA 22202.

Contact Person: Mary C. Custer, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–2620.

Name of Committee: Neuropharmacology Research Subcommittee.

Date: February 17–19, 1998.

Time: 8:30 a.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Syed Husain, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–2620.

Name of Committee: Treatment Research Subcommittee.

Date: March 2–4, 1998.

Time: 8:30 a.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Kesinee Nimit, M.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–9042.

Name of Committee: NIDA Special Emphasis Panel (Training and Career Development).

Date: March 2–4, 1998.

Time: 8:30 a.m.