Programs, and (2) Performance Progress Report for RF Programs; and

• Quarterly Performance Report (QPR), with two versions: (1) Quarterly Performance Progress Report for HM Programs, and (2) Quarterly Performance Progress Report for RF Programs.

Grantees in the new cohort will also be required to engage in continuous quality improvement (CQI) planning and implementation using a proposed CQI plan template developed by ACF. The estimated burden for completing and updating this template is included in the table below.

Respondents: Respondents include HM and RF grantee staff and program applicants and participants (participants are called ''clients'').

ANNUAL BURDEN ESTIMATES

Instrument	Respondent	Number of respondents (total over request period)	Annual number of respondents	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
1: Applicant Characteristics	Program applicants	273,839	91,280	1	0.25	68,460	22,820
	Program staff	408	408	224	0.10	27,384	9,128
2: Program Operations	Program staff	136	136	12	0.32	526.32	175.44
3: Service Delivery Data	Program staff	2,040	2,040	126	0.50	128,706	42,902
4: Entrance and Exit Surveys	Program clients (entrance)	257,409	85,803	1	0.42	108,111.78	36,037.26
	Program clients (exit)	169,965	56,655	1	0.42	71,385	23,795
	Program staff (entrance and exit on paper).	32	32	1,169	0.10	11,220	3,740
5: Semi-annual Performance Progress Report (PPR).	Program staff	136	136	6	3	2,448	816
6: Quarterly Performance Report (QPR).	Program staff	136	136	6	1	816	272
7: CQI Plan	Program staff	136	136	3	4	1,632	544

Estimated Total Annual Burden Hours: 140,230.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 403. [42 U.S.C. 603].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–26266 Filed 11–27–20; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1337]

John Kapoor: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring John Kapoor from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that John Kapoor was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. John Kapoor was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. Mr. Kapoor, through counsel, submitted a letter to FDA, which commented on some of the factual circumstances surrounding the case. In the letter, he also stated that he did not intend to request a hearing nor, however, would he acquiesce to debarment. As of August 26, 2020 (30 days after receipt of the notice), Mr. Kapoor has not requested a hearing. His failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable November 30, 2020.

ADDRESSES: Submit applications for special termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, (ELEM–4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, *debarments@fda.hhs.gov,* 240–402–8743.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On January 23, 2020, Mr. Kapoor was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against him in the U.S. District Court for the District of Massachusetts, after a jury verdict, to one count of Racketeering Conspiracy in violation of 18 U.S.C. 1962(d). The pattern of racketeering activity he was convicted of included engaging in multiple acts of mail fraud (18 U.S.C. 1341) and wire fraud (18 U.S.C. 1343).

The factual basis for this conviction is as follows: Mr. Kapoor was the founder and majority owner of Insys Therapeutics Inc. (Insys), a Delaware Corporation, with headquarters in Chandler, Arizona. In addition, he held executive management positions at Insys, including Executive Chairman of the Board of Directors and, for a time,

Chief Executive Officer (CEO). Insys developed and owned a drug called SUBSYS, a liquid formulation of fentanyl to be applied under the tongue. FDA approved SUBSYS for the management of breakthrough pain in adult cancer patients who are already receiving and are already tolerant to opioid therapy for their underlying persistent cancer pain. From 2012 and continuing through 2015, Mr. Kapoor oversaw a conspiracy whereby employees of Insys bribed medical practitioners in various states to get those practitioners to increase prescribing SUBSYS to their patients. Mr. Kapoor, along with his co-conspirators, measured the effect of these bribes on each practitioner's prescribing habits and on the revenue that each bribed practitioner generated for Insys. Mr. Kapoor, along with his co-conspirators, reduced or eliminated bribes paid to those practitioners who failed to meet the minimum prescription requirements or failed to generate enough revenue to justify additional bribes.

To further this conspiracy, Mr. Kapoor oversaw a scheme whereby Insys executives conspired to mislead and defraud health insurance providers to ensure those providers approved payment for SUBSYS. Insys achieved this goal by establishing the ''Insys Reimbursement Center,'' which was designed to shift the burden of seeking prior authorization for SUBSYS from practitioners to Insys. This allowed Insys to determine what medical information was presented to insurers. Mr. Kapoor and his co-conspirators directed Insys employees to mislead insurers to obtain payment authorization.

As a result of this conviction, FDA sent Mr. Kapoor by certified mail on July 16, 2020, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Kapoor was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Kapoor an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Kapoor received the proposal on July 27, 2020. Mr. Kapoor, through counsel, submitted a letter to FDA dated August 12, 2020, which commented on some of the factual circumstances surrounding the case. In the letter, he also stated that he did not intend to request a hearing nor, however, would he acquiesce to debarment. Since he did not request a hearing within the timeframe prescribed by regulation, Mr. Kapoor has waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Kapoor has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Kapoor, is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Kapoor, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Kapoor provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Kapoor during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (see section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Kapoor for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2020–N–1337 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26262 Filed 11–27–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4248]

Barry J. Cadden: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Barry J. Cadden from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Cadden was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Cadden was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. As of July 9, 2020 (30 days after receipt of the notice), Mr. Cadden had not responded. Mr. Cadden's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable November 30, 2020.

ADDRESSES: Submit applications for special termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, *debarments@fda.hhs.gov,* or at 240–402–8743.

SUPPLEMENTARY INFORMATION: