THE CRIME OF DOING NOTHING: NEW THREATS FOR CORPORATE OFFICERS

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The Crime of Doing Nothing

The Responsible Corporate Officer Doctrine: New and Evolving Threats

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Overview of the Doctrine

It started as a rarely-used theory for imposing strict criminal liability for FDA misdemeanors, but the Responsible Corporate Officer Doctrine ("RCO doctrine") has developed into a way of establishing the liability of corporate officers and other responsible individuals for administrative and civil penalties. Aptly called the "crime of doing nothing," the RCO doctrine focuses on a person's *position* in an organization as a basis for imposing a non-delegable duty to prevent violations that could harm the public.

Overview of the Doctrine (cont'd)

- *U.S. v. Dotterweich* and *U.S. v. Park* (1975) are the seminal RCO doctrine decisions by the Supreme Court. They stand for the proposition that corporate misconduct and violations of law can result in the conviction of organization executives without individual involvement in wrongdoing or even knowledge it was taking place.
  - The RCO doctrine was recently applied in cases involving violations of law that protect the health and safety of Medicare and Medicaid beneficiaries (*e.g.*, Purdue Frederick, Inc. – which involved the promotion of the "off-label" use of Oxycontin).

Overview of the Doctrine (cont'd)

- Individual criminal (i.e., plea to misdemeanor conviction), civil (i.e., individual multi-million dollar fines), and administrative (Federal health program exclusion) liability for the CEO, GC and CMO.
- Individual criminal, civil and administrative liability against Purdue executives was not based on their personal involvement or even their knowledge of organization wrongdoing.
- Rather, it was based on the RCO doctrine whereby each executive had "responsibility and authority to prevent or to promptly correct the organizational misconduct."

Overview of the Doctrine (cont'd)

- The RCO doctrine *presumes* that someone in a position of responsibility at a company has both the power and the duty to prevent violations that may endanger the public.
- RCO liability is based on a person's *status* and imposed *vicariously*. By *imputing* a duty to prevent a violation of a public welfare law, this doctrine extends beyond state statutes that criminalize the *failure to act if a specific duty to act is imposed by statute*.

Overview of the Doctrine (cont'd)

- The RCO doctrine also extends liability beyond various common law theories that impose *civil* liability against directors and officers. For instance, while a director will be safe from *civil* liability by operation of the "business judgment rule" if s/he fulfills his or her *Caremark* oversight duties, he or she can be *criminally* responsible by operation of the RCO doctrine *even if* s/he lacked knowledge that employees violated public welfare laws.

Overview of the Doctrine (cont'd)

- Courts have rejected arguments that corporate officers delegated the responsibility to prevent such misconduct. As noted, under the RCO doctrine, delegation is not a defense; but powerlessness is—it's just not easily shown. Courts have been hostile to such arguments. *See, e.g., State v. Rollfink*, 475 N.W.2d 575, 580 (Wis. 1991) ("Since delegation is done by those with a broad range of responsibilities, [it] shows that the defendant was responsible for the overall operation of [the company's] facility").

Scope of the Doctrine

- While the doctrine is particularly dangerous to individuals working in industries affecting the public welfare, such as pharmaceutical companies and other healthcare entities, it has expanded to cover environmental and other violations as well. For instance, in the *Nature's Sunshine* case, the SEC imposed liability under the FCPA's "books and records" provisions using the RCO doctrine against "control persons" who lacked knowledge of wrongdoing by employees of a foreign subsidiary. It has also been used recently by the agency in "clawback" actions.

Legacy of Organizational Accountability Deemed Insufficient to Curtail Fraudulent and Abusive Practices

- Government officials have expressed concerns that organizations view fines, penalties, DPA's and CIA's in the health care industry as a cost of doing business -- and these sanctions aren't deterring fraudulent and abusive conduct.
- So, recent enforcement actions have targeted organization executives in various ways for criminal, civil and administrative liability based on organizational misconduct:

Legacy of Organizational Accountability Deemed Insufficient to Curtail Fraudulent and Abusive Practices (cont'd)

- The assumption is that organizational misconduct cannot occur without individual involvement;
- What individuals are responsible for organizational misconduct?;
- Responsible Corporate Officer Doctrine.

Legacy of Organizational Accountability Deemed Insufficient to Curtail Fraudulent and Abusive Practices (cont'd)

- The RCO Doctrine is *strict liability*: There is no need to establish personal involvement in the misconduct to have criminal and administrative liability for misdemeanors and exclusion
  - Pharma and Medical Device Industry for FDCA violations (Purdue Frederick and Synthes, Inc.)
  - Exposure for health care organizations' board members and upper level management who are responsible for and have the authority to prevent or correct noncompliant activity.

Legacy of Organizational Accountability Deemed Insufficient to Curtail Fraudulent and Abusive Practices (cont'd)

- Federal Health Care Program Exclusion can also be based on the RCO Doctrine:
  - No knowledge of, or participation in the core activity is required
  - A 12-year exclusion of a CEO, GC, and CMO has been upheld. See *Friedman v. Selbelius*, 2010 U.S. Dist. Lexis 131465 (D.D.C. December 13, 2010), appeal pending before the D.C. Circuit Court of Appeals.

Synthes / Norian

- Charges were brought against Synthes, its subsidiary Norian Corp. and four of its former executives as to alleged off-label promotion and unapproved clinical trials conducted using a Norian bone cement.
  - Criminal Pleas: Synthes (misdemeanor); Norian (felony and misdemeanors); 4 former executives (misdemeanors as responsible corporate officers). All were sentenced to jail time
  - Civil Settlement Agreement
  - Corporate Integrity Agreement with Synthes
  - Divestiture Agreement with Synthes for the divestiture of Norian assets

Purdue Pharma

- A subsidiary entity pled guilty to felony misbranding of Oxycontin with the intent to defraud or mislead.
- The company's former President and CEO, Chief Legal Officer and Chief Medical Officer were convicted of misbranding offenses as responsible corporate officers.
- The OIG excluded the executives under Section 1128(b)(1) and (b)(3) based upon their convictions.
- Their 12-year exclusions were upheld by the District Court (December 2010).

KV Pharmaceuticals

- March 2010: KV Pharmaceuticals subsidiary Ethex was convicted of a mandatory exclusion offense.
- Criminal Information: "Executive A" decided not to report manufacturing problems to FDA.
- The OIG excluded Marc Hermelin, KV's former CEO and substantial owner, under section 1128(b)(15)(i). KV was subject to potential exclusion under section 1128(b)(8).
- The OIG, KV, and Hermelin reached a settlement whereby Hermelin resigned from KV's board and divested ownership.

Impact on Compliance and Governance

- *A*gencies' reliance on the responsible corporate officer doctrine *directly impacts compliance programs and corporate governance oversight responsibilities.*

  Compliance programs enhance the RCO doctrine's deterrence objectives because they are a sharper instrument for achieving accountability. The RCO doctrine casts its net so broadly that it risks diluting its underlying policy objectives by making so many individuals potentially responsible that no individual perceives himself as invested in ensuring compliance.

Douglass, *The (Ir)Responsible Corporate Officer Doctrine and Contemporary Corporate Compliance: Protecting Responsible Corporate Officers from Irresponsible Prosecution* (Jan. 2011).

FDA's Guidance on the RCO Doctrine

- The FDA's recent guidance entitled "Special Procedures and Considerations for *Park* Doctrine Prosecutions" lists seven factors that the agency will consider in determining whether to recommend that the RCO doctrine should be applied.
- The agency's guidance is notable in placing the burden on responsible individuals to show otherwise.

FDA's Guidance (cont'd)

- **The seven non-exclusive factors are:**
  - Whether the violation involves actual or potential harm to the public;
  - Whether the violation is obvious;
  - Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
  - Whether the violation is widespread;
  - Whether the violation is serious;
  - The quality of the legal and factual support for the proposed prosecution; and
  - Whether the proposed prosecution is a prudent use of agency resources.

OIG's Guidance on its Exclusion Authority

- In late 2010, the OIG for HHS provided guidance regarding its *derivative* exclusion authority under Section 1128(b)(15) against the owners, managers, and executives of healthcare providers. See http://oig.hhs.gov/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

OIG Exclusion

- Payment Prohibition: No program payment may be made for any items or services furnished, ordered, or prescribed by an excluded individual or entity.
- The OIG for HHS has four *mandatory* exclusion authorities and sixteen *permissive* (discretionary) authorities

Permissive Exclusion of Individuals Under Section 42 U.S.C. § 1320a-7(b)(15)

- One of OIG's 16 bases for permissive exclusion
- Section 1128(b)(15) authorizes the exclusion of certain individual owners and officers and managing employees of a "sanctioned entity"
  - Individuals with **ownership or control interest** in sanctioned entity may be excluded if they *knew or should have known* of conduct that led to the sanction.
  - **Officers and managing employees** may be excluded solely based on their *position* with the sanctioned entity.

Exclusion of Officers/Managers under Section 1128(b)(15)(A)(ii)

- Four categories of information are to be considered:
  - The Circumstances/Seriousness of the Offense;
  - The Individual's Role in the Sanctioned Entity;
  - The Individual's Actions in Response to Misconduct; and
  - Information about the Entity

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Questions?

Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act

SUMMARY: This notice sets forth nonbinding factors the Office of Inspector General (OIG) will consider in deciding whether to impose permissive exclusion in accordance with section 1128(b)(15)(A)(ii) of the Social Security Act (the Act), which authorizes OIG to exclude an officer or managing employee of an entity that has been excluded or has been convicted of certain offenses.

SUPPLEMENTARY INFORMATION

I. Purpose and Rationale

Section 1128(b)(15) of the Act authorizes the Secretary, and by delegation the Inspector General, to exclude an individual owner, officer, or managing employee of a sanctioned entity, as defined in section 1128(b)(15)(B) (i.e., an entity that has been convicted of certain offenses or excluded from participation in the Federal health care programs). Exclusions under section 1128(b)(15) of the Act are derivative in nature and are based upon the individual's role or interest in a company that is excluded or is convicted of certain offenses. Exclusions under section 1128(b)(15) are permissive, that is, the Secretary has the discretion whether to exclude or not to exclude. OIG's exercise of this discretion is not subject to administrative or judicial review.

Section 1128(b)(15) of the Act provides two different bases for exclusion. Individuals who have an ownership or a control interest in a sanctioned entity may be excluded under section 1128(b)(15)(A)(i) if they knew or should have known of the conduct that led to the sanction. Officers and managing employees, as defined in section 1126(b) of the Act, may be excluded under section 1128(b)(15)(A)(ii) based solely on their position within the entity.

Because the elements of these two provisions are so different, our exclusion analysis differs depending on whether the individual in question is: (1) an owner or (2) an officer or a managing employee.

The statute sets a higher standard for exclusion of an owner, requiring evidence that the owner knew or should have known of the conduct that formed the basis for the sanction. In general, if the evidence supports a finding that an owner knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. This presumption may be overcome when OIG finds that significant factors weigh against exclusion.

With respect to officers and managing employees, the statute includes no knowledge element. Therefore, OIG has the authority to exclude every officer and managing employee of a sanctioned entity. A "managing employee" is defined as an individual (including a general manager, a business manager, an administrator, or a director) who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity. While OIG does not intend to exclude all officers and managing employees, when there is evidence that an officer or a managing employee knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. As with the presumption relating to owners, the presumption may be overcome when OIG finds that significant factors weigh against exclusion.

OIG will consider the factors set forth below in deciding whether to exclude an officer or a managing employee in the absence of evidence that the person knew or should have known of the misconduct. We believe that these factors will serve a number of useful purposes: (1) they will allow for the development of effective investigations and investigative plans by OIG and its law enforcement partners, (2) they will establish and publicize a framework that will serve as a basis for OIG's permissive exclusion decisions, (3) they will allow for the appropriate allocation of OIG's finite resources to actions that have the most remedial and deterrent effect, and (4) they will positively influence individuals' future behavior and compliance with Federal health care program requirements by holding individuals accountable for misconduct within entities in which they are in positions of responsibility.

These factors are internal agency guidelines that may be subject to modification at any time. They are not intended to limit OIG's discretionary authority to exclude individuals or entities that pose a risk to Medicare and other Federal health care programs or program beneficiaries, nor do they create any rights or privileges in favor of any party. Further, these factors do not supplant or modify, in any way, the OIG regulations, codified at 42 CFR part 1001, governing program exclusions.

These factors were derived from multiple sources, including: (1) the regulations governing exclusions under sections 1128(b)(15) and 1128A of the Act (42 CFR parts 1001 and 1003); (2) the factors for implementation of permissive exclusion under section 1128(b)(7) (62 Fed. Reg. 67392 (Dec. 17, 1997)); (3) the responsible corporate official doctrine established in case law, including *U.S. v. Park*, 421 U.S. 658 (1975); and (4) decisions of the Departmental Appeals Board in exclusion matters.

II. Factors To Be Considered in Implementing OIG's Permissive Exclusion Authority Under Section 1128(b)(15)(A)(ii)

OIG may use the following factors to determine whether to impose a permissive exclusion under section 1128(b)(15)(A)(ii) of the Act in a particular case. They are

informal and nonbinding. The presence or absence of any or all of these factors does not constitute the sole grounds for determining whether OIG will pursue exclusion.

When considering whether to exclude an individual under section 1128(b)(15), OIG will consider the basis for the criminal conviction and/or exclusion of the entity, as well as any other conduct that formed the basis for criminal, civil, or administrative investigations, cases, charges, or resolutions. In addition, OIG will consider matters that involve entities that are or were related to the convicted or excluded entity. For example, OIG will consider the conduct alleged by the Government in a civil False Claims Act settlement with a corporate parent of the convicted or excluded entity. As used in the following factors, the term "misconduct" includes the factual basis for the criminal conviction or exclusion that underlies the potential 1128(b)(15) exclusion as well as any other conduct OIG considers relevant, including allegations in criminal, civil, and administrative matters involving the convicted or excluded entity or any related entity.

A. Circumstances of the Misconduct and Seriousness of the Offense

1. What were the nature and scope of the misconduct for which the entity was sanctioned? What were the nature and scope of any other relevant misconduct? At what level of the entity did the misconduct occur (e.g., violation by one field employee of company policy versus headquarters' involvement and/or direction)?

2. What was the criminal sanction imposed against the entity (or related entities) or any individuals? What was the amount of any criminal fine, forfeiture, or penalty imposed? What was the amount of any civil or administrative payment regarding related or similar issues? What was the length of any period of exclusion imposed?

3. Was there evidence that the misconduct resulted in (1) actual or potential harm to beneficiaries or other individuals or (2) financial harm to any Federal health care program or any other entity? If financial loss to the programs or other persons occurred, what was the extent?

4. Was the misconduct an isolated incident or part of a pattern of wrongdoing over a significant period of time? Has the entity previously had similar problems with OIG, the Centers for Medicare & Medicaid Services or its contractors, or any other Federal or State regulatory agency? What was the nature of these problems?

B. Individual's Role in Sanctioned Entity

1. What is the individual's current position? What positions has the individual held with the entity throughout his or her tenure, particularly at the time of the

underlying misconduct? What degree of managerial control or authority is involved in the individual's position?

2. What was the relation of the individual's position to the underlying misconduct? Did the misconduct occur within the individual's chain of command?

C. Individual's Actions in Response to the Misconduct

1. Did the individual take steps to stop the underlying misconduct or mitigate the ill effects of the misconduct (e.g., appropriate disciplinary action against the individuals responsible for the activity that constitutes cause for the sanction or other corrective action)? Did these actions take place before or after the individual had reason to know of an investigation? If the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, OIG may consider this as a factor weighing against exclusion.

2. Did the individual disclose the misconduct to the appropriate Federal or State authorities? Did the individual cooperate with investigators and prosecutors and respond in a timely manner to lawful requests for documents and evidence regarding the involvement of other individuals in a particular scheme?

D. Information About the Entity

1. Has the sanctioned entity or a related entity previously been convicted of a crime or found liable, civilly or administratively, or resolved a civil or administrative case with the Federal or State Government or a government entity? If so, what was the prior conduct that formed the basis for these actions?

2. What is the size of the entity (e.g., how many employees does the entity have, what are the revenues, how many product lines/divisions are there within the entity)? What is the corporate structure of the entity (e.g., how many subsidiaries (operating and nonoperating) are there, what are the sizes of the subsidiaries, and what are the reporting relationships between the subsidiaries)?

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U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

6-5 - PROSECUTION

6-5 - PROSECUTION

6-5-1 - Purpose

This section establishes guidelines for the uniform submission and review of prosecution recommendations, including referrals for criminal investigation. A number of different procedures, depending upon the distinguishing case features, are included in order to eliminate unnecessary review and to expedite the case review process.

As described below, all criminal referrals, whether initiated by the District, the Center, or another FDA Headquarters component, must be sent to OCI for initial review in accordance with Section 6-5-2 and 6-5-3. If OCI declines the referral, the Center or District may pursue the matter through the preparation of a Summary and Recommendation in accordance with Section 6-5-5 et seq.

6-5-2 - Referral of Criminal Matters to the Office of Criminal Investigations

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters. FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and Section 305 meetings.

District management must communicate with the local OCI office before pursuing any criminal matter. Designated center and ORA and FDA Headquarters points of contact must communicate with their respective OCI Senior Operations Manager (SOM). This communication is absolutely essential to preclude potential interference with other on-going criminal investigations and to prevent confusion among the components of the Office of Chief Counsel and the Department of Justice that are responsible for handling FDA's criminal cases.

During this communication, OCI is to be provided with all of the facts of the potential case and any additional information that is relevant to, or could impact, the case in any way. In accordance with SMG 9111, district management should notify the local Special Agent in Charge, Assistant Special Agent in Charge, or Resident Agent in Charge of the referral via telephone. For referrals of Park Doctrine prosecutions, see the procedures below.

For all criminal referrals, OCI will decide promptly whether or not to pursue the case. OCI will communicate its decision back to the referring Office. If OCI declines to pursue a referral, OCI will promptly convey its decision to the referring office, which may then proceed with the case and submit a formal summary and recommendation for prosecution in accordance with sections 6-5-5 and 6-5-13 of this chapter.

6-5-3 - Special Procedures and Considerations for Park Doctrine Prosecutions

Recommending Park Doctrine Prosecutions

The Park Doctrine, as established by Supreme Court case law, provides that a responsible corporate official can be held liable for a first time misdemeanor (and possible subsequent felony) under the Federal Food, Drug, and Cosmetic Act ("the Act") without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense. A Park Doctrine prosecution, for the purposes of this section, refers to a recommended prosecution of a responsible corporate official for a misdemeanor violation of the Act.

Misdemeanor prosecution under the Act can be a valuable enforcement tool. Such prosecutions are referred to the Department of Justice. Once a person has been convicted of a misdemeanor under the Act, any subsequent violation of the Act is a felony, even without proof that the defendant acted with the intent to defraud or mislead. Misdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities. In some cases, a misdemeanor conviction of an individual may serve as the basis for debarment by FDA.

When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to

recommend charging a misdemeanor violation.

Other factors to consider include but are not limited to:

1. Whether the violation involves actual or potential harm to the public;
2. Whether the violation is obvious;
3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
4. Whether the violation is widespread;
5. Whether the violation is serious;
6. The quality of the legal and factual support for the proposed prosecution; and
7. Whether the proposed prosecution is a prudent use of agency resources.

As the Supreme Court has recognized, it would be futile to attempt to define or indicate by way of illustration either the categories of persons that may bear a responsible relationship to a violation or the types of conduct that may be viewed as causing or contributing to a violation of the Act. In addition, these factors are intended solely for the guidance of FDA personnel, do not create or confer any rights or benefits for or on any person, and do not operate to bind FDA. Further, the absence of some factors does not mean that a referral is inappropriate where other factors are evident.

When a district office is considering initiating a referral for a Park Doctrine prosecution, the district is required to consult with the appropriate center to ensure that the referral will align with agency priorities and that the center will support the referral and provide expert witnesses or other litigation support when necessary. Centers and district offices are also encouraged to consult with OCC and OCI HQ Special Agent in Charge (SAIC) and/or the Assistant Special Agent in Charge (ASAIC) Investigative Operations Division (IOD) early in the process for guidance and recommendations regarding optimal venue.

If the district or center is seeking a misdemeanor prosecution under the Park Doctrine, the initial referral to OCI should clearly indicate that a Park Doctrine prosecution is being sought and the reasons that a Park Doctrine prosecution would be beneficial. At the same time that the district refers a Park Doctrine prosecution to an OCI Field Office, notice of the referral also should be sent to the SAIC and/or the ASAIC OCI HQ IOD, and the applicable center. Notice of all Park Doctrine referrals, whether initiated by the district office or the center, should also be sent to the Deputy Chief Counsel and Associate Deputy Chief Counsel for Litigation in the Office of Chief Counsel (OCC), and the director of the Office of Enforcement.

Upon receipt of a Park Doctrine referral, OCI will promptly review the referral and will communicate with OCC and the referring office to obtain any information or assistance needed to present the matter for prosecution. In appropriate cases, the assigned OCC attorney and/or a representative from the Office of Enforcement or other component should participate in the initial presentation of the Park Doctrine matter.

6-5-4 - Communication Between OCI and Other FDA Components

The following Staff Manual Guides (SMGs) provide additional information on communications between OCI and other FDA components:

1. SMG 9111 Sharing of Information Related to Criminal Violations - http://www.fda.gov/About FDA/ReportsManualsForms/StaffManualGuides/ucm212504.htm [1] – This SMG requires that OCI be notified of potential criminal activity immediately if there is an imminent threat to public health and within 10 business days in all other cases and that OCI evaluate the information within 10 business days and notify the district office of its initial assessment. It also addresses information sharing between OCI and other FDA components.
2. SMG 9110 Enhanced Communications with the Office of Criminal Investigations (OCI) and Improved Alignment of Criminal/Regulatory Priorities and Activities – http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm212503.htm [2] - This SMG provides general procedures for the establishment of regularly scheduled meetings between OCI and center, ORA and other FDA components.

Notify OCI if you receive a request from a law enforcement agency (federal, state/local, or foreign) for non-public information related to a criminal case. Notification should be provided to the SAIC and/or the ASAIC, OCI HQ IOD. This is particularly important if the request relates to grand jury information, judicial proceedings under the Federal Food, Drug, and Cosmetic Act, or joint investigations with OCI and other law enforcement agencies about violations of the Federal Food, Drug, and Cosmetic Act. When OCI seeks non-public information on its own initiative or in response to a request described above, provide the information to the SAIC and/or the ASAIC OCI HQ IOD for their review and determination of appropriate written confidentiality assurances prior to disclosure. Indicate what information is non-public.

6-5-5 - Processing a Summary and Recommendation

In cases where OCI has declined to pursue a referral, the recommendation for prosecution or for investigation with a view of possible criminal charges will be prepared in the format of a Summary and Recommendation (S&R). This document is a memorandum containing all information that would permit review and evaluation of the district's recommendation, including the reasons for not including samples or individuals cited in the Section 305 notice (when such a notice is issued) and information concerning any potential weaknesses in the case, anticipated defenses, or reasons why discretion may be exercised not to prosecute a person (such as, extreme age or very poor health).

It is important for the S&R to contain all facts pertaining to the recommendation, since it will be relied upon to determine whether a case is prosecutable and worthy of forwarding to the Department of Justice (DOJ). In prosecution cases in which FDA forwards counts in an Information or Indictment (as opposed to referrals for criminal investigation), the S&R should present the evidence of **each element** of the offense to be charged.

Where a district submitted the original referral or where the referral relates to an inspectional process, each recommendation must be accompanied by the written concurrence of the District Director (DD) and the Regional Food and Drug Director (RFDD). The DD's approval must state why prosecution is the action of choice, and the RFDD must concur. This concurrence will appear on the last page of the S&R. Where a center submitted the original referral and the referral relates to a center process, each recommendation must be accompanied by the written concurrence of the director of the center's office of compliance.

See section 6-5-13 for detailed guidance for preparing an S&R.

6-5-6 - Criminal Prosecution after Section 305 Notice

Criminal referrals for which the agency has provided a notice and opportunity to respond, pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act (the Act), should follow the procedures described below:

1. When a district does not have direct reference authority to issue a Section 305 notice, the district will submit a citation recommendation to the appropriate center(s) for review, after contacting OCI (as described in "Office of Criminal Investigations" above. Generally, the citation recommendation includes:
    a. the names and responsibilities of each individual and the charges to be presented in the notice;
    b. the full background history of notification of the persons to receive a notice; and,
    c. facts supporting the proposed charges, including assurance of interstate documentation. All pertinent evidence, such as work sheets, labels, and inspection reports, should be submitted with the recommendation. The center may request the interstate documentation if a special need to review it exists.

2. If the district or the center identifies an issue requiring consultation with the Office of Enforcement (OE), OCI, Office of the Chief Counsel (OCC), or an ad hoc committee, the component identifying the issue will obtain prompt resolution as early in the review process as possible.
3. If, following the meeting held in response to the Section 305 notice, there is no significant change in the facts, as set forth in the district's citation recommendation, the district will notify the center, which will promptly forward the district's citation recommendation package to the Division of Compliance Management and Operations (DCMO), in OE. Concurrently, a final S&R will be sent by the district to DCMO with copies to the center.

   If there is a significant change in the facts or strength of the proposed case, the district will submit the prosecution recommendation package to the appropriate center solely to determine whether prosecution remains warranted in view of the new information. If prosecution is warranted, the center will promptly forward to DCMO the prosecution S&R and the center's approval memo presenting the basis for its decision in light of the new information.

   NOTE: When a district has evidence sufficient to meet the requirements for direct reference authority to issue a Section 305 notice ("direct reference cite authority"), the procedures in # 1 above do not apply. (Except that OCI must be contacted, as described in "Office of Criminal Investigations" above.) After the Section 305 process has been completed and, if no new information is presented that affects the basis for the direct reference authority, the district should promptly submit its prosecution S&R directly to DCMO for a limited review. The district should concurrently send a copy of the S&R to the center.

   If the response to the Section 305 notice reveals new information affecting the basis for the direct reference cite authority, the district must obtain center review and concurrence concerning that aspect of the recommendation before submitting it to DCMO.
4. DCMO will perform a limited review to determine whether the proposed prosecution conforms to agency policy and enforcement strategies and objectives. If DCMO concurs in the prosecution recommendation, it will forward all relevant materials to OCC, along with a memo concerning the issues it has considered and that DCMO believes OCC should review.
5. OCC will review the recommendation and, if it agrees that prosecution is supportable, prepare a referral letter and form of Information or Indictment.

6-5-7 - Criminal Prosecution without Section 305 Notice

Those instances in which the agency need not issue a Section 305 notice under the Act are codified in 21 CFR 7.84. No Section 305 notice is required in cases brought under Title 18 of the United States Code - as opposed to cases brought under the Act - or in cases exempt under 21 CFR 7.84(a)(2) and (3), based on the agency's belief that the notice might result in alteration or destruction of evidence or flight to avoid prosecution. Nor is a Section 305 notice usually provided when the agency is recommending further investigation.

Criminal referrals not preceded by a Section 305 notice should follow the procedures described below. OCI must be contacted early on in this process, in accordance with the procedures described in "Office of Criminal Investigations" above.

1. The district is to consult with DCMO, which will consult with OCC, to determine whether to issue a Section 305 notice or whether an ad hoc committee is needed to decide the issue. If DCMO and OCC agree that no Section 305 notice should be issued, DCMO will so notify the district. The district will then prepare an S&R and obtain approval from the Region before submitting the S&R to DCMO, with concurrent copies to the center and OCC for review. The district will explain under the heading "No Section 305 Notice" why such notice is not required. (Should DCMO and OCC decide that a Section 305 notice should be issued, DCMO will so notify the district who will then follow the procedure under RPM, "Prosecution after 305 Notice".)
2. If the center and DCMO concur in the recommendation, each will prepare a memo reflecting its views on the relevant issues. The center will forward its memo to DCMO.
3. DCMO will forward all relevant materials and memos to OCC and, if OCC agrees that prosecution is supportable, OCC will prepare a referral letter and form of Information or Indictment.

6-5-8 - Contempt Of Court; Violation of Probation

The district will prepare an S&R outlining the facts that establish the violative conduct and send it and a copy of the pertinent court order electronically via CMS to DCMO. Because DCMO and the relevant center are expected to conduct concurrent reviews, the S&R should include a request that DCMO send a task referral pursuant to CMS procedures to the center requesting its review.

Both the center and DCMO will have 10 working days to review the proposed action and upload their comments into CMS.

If no adverse comment is provided by either the center or DCMO, or if adverse comment was provided but a consensus to proceed is reached, the district will forward its S&R and supporting evidence to DCMO via CMS for prompt forwarding to OCC for review. If OCC agrees that the action is supportable, it will prepare a referral letter.

6-5-9 - Development of Felony Violation

Some investigations may reveal facts supporting potential felony charges under either Title 18 of the United States Code or 333(a)(2) of Title 21. A primary problem associated with these cases is determining the investigational end-point. When such situations are encountered, an ad hoc committee should be considered. This is because some potential cases should be referred at an early stage for a grand jury investigation, while FDA can carry others to investigational completion, prior to referral.

The following matters, among others, should be considered in these situations:

1. scope of the investigation;
2. status of current investigation, including identification of targets and of potential cooperating individuals;
3. strategy and timing in completing the investigation;
4. agency compliance policy in the area at issue;
5. preliminary evidence that violations are intentional;
6. identification of inspectional or investigational problems;
7. use of criminal search warrants;
8. need for or wisdom of a Section 305 notice citation; and,
9. recommendation for grand jury investigation (see RPM "Grand Jury Investigations").

For investigations subject to ad hoc committee oversight, the compliance branch in the managing organizational unit will prepare a status report whenever significant progress is made on an investigation or at least every 90 calendar days, whichever occurs first, and distribute it to DCMO, OCC, appropriate center, and affected regional/district offices.

6-5-10 - Referrals for Criminal Investigation

A referral from a district or center to DOJ for further criminal investigation, including an investigative grand jury, should follow the process

described below:

1. The initiating unit, district or center, will notify OCI in accordance with the RPM section "Office of Criminal Investigations." If OCI elects not to pursue the case, then the district or center may notify DCMO and request an ad hoc committee meeting, and provide a Summary and Recommendation Document (S&R) of the existing evidence. Relevant, organized, and tabbed background material will be assembled by the initiating unit and uploaded with the S&R into CMS. The district should transfer the case to DCMO by changing the current owner to DCMO pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DCMO designated to receive notification when ownership of a case has changed to that office. Information should cross reference and cite specific pages of the background material.
2. Prior to scheduling the meeting, DCMO will review the background package and ensure that it is in a form that will facilitate review and identification of issues.
3. DCMO will promptly notify the committee via e-mail of the availability of the background package in CMS and in the body of the e-mail provide a time and place for the meeting, and identify the principal issues to be decided. With very rare exception, a minimum of 10 working days will be provided for members to review the background package; center review will be given high priority and the meeting will not be scheduled until the center is ready to participate. A copy of this e-mail should be uploaded into CMS.
4. The committee members should be prepared to make agency decisions on the issues, including whether referral should be made on the basis of the evidence in hand, whether additional assignments should first be issued, completed, and reviewed by the committee, or whether a noncriminal disposition should be considered in lieu of or in addition to a prosecution.
    a. Should the committee members concur in the recommendation for referral and believe that there is no need to gather further evidence or for a further meeting, DCMO will promptly prepare a memorandum of the decision, upload it into CMS and forward a hardcopy to OCC as the agency's recommendation. DCMO will maintain ownership of the case. OCC will revise the district's draft of the referral letter, as necessary. DCMO should upload this draft into CMS.
    b. Should the committee believe that additional investigation is needed, the committee will issue the appropriate assignments, record them in a memo that is uploaded in CMS and set a tentative date to reconvene. Offices performing the additional work will be responsible for providing written summaries of the results and, when appropriate, recommendations to the committee in advance of the next meeting. These associated documents should be uploaded into CMS. DCMO will monitor the status of the assignments and schedule via e-mail the follow-up meeting. A minimum of 5 working days will be provided for members to review new information prior to the meeting. DCMO will prepare a memorandum of any subsequent meeting and upload it into CMS.
5. If the committee decides, either on the basis of its initial review or on the basis of additional data discussed at a subsequent meeting, that a request for criminal investigation should be referred, DCMO will promptly forward to OCC any relevant materials that may not have previously been provided along with a written request that OCC refer the matter to DOJ.

    NOTE: When FDA participates in investigations in which another Federal agency has the lead and intends to request a criminal investigation, the district will work directly with the lead agency in developing evidence and in assisting in the investigation. In such cases, the district will promptly notify the relevant centers, DCMO, OCI, and OCC of the investigation, the district's role in it, and whether a grand jury investigation is contemplated.

    As soon as the district determines that it would like to seek the prosecution of Title 21 or Title 18 charges based upon violations involving FDA regulated articles in an investigation where another Federal agency has the lead, it will notify DCMO, for an FDC number, the centers, and OCC of its intent to do so and will promptly forward a recommendation to DCMO, the center or, if appropriate, directly to OCC, to obtain approval to proceed with the case.

    In some cases, an ad hoc meeting may be appropriate. If special time constraints are applicable because of the participation of other agencies, the recommendation should so state. Except for possible time constraints, joint investigations should be processed in the same manner as other FDA cases.

6-5-11 - Information And Indictments

These documents will usually be prepared by Office of Chief Counsel.

An Information is the formal legal document that is usually used to allege misdemeanor violations. An Indictment is the document in which felony violations are alleged, following presentation to the grand jury. This document is also referred to as a True Bill of Indictment. With the consent of a defendant, an Information may be presented to a grand jury, even though only misdemeanor violations are alleged.

6-5-12 - Grand Jury Investigations And Secrecy

Grand jury investigations are subject to Rule 6 of the Federal Rules of Criminal Procedure (see Exhibit 6-29). The fact of grand jury investigations and the actions of a Federal grand jury are secret. Only persons whose names have been filed with the court pursuant to Rule 6(e) may know about the grand jury's activities, such as whether the grand jury has issued a subpoena to someone. **For this reason, transcripts of testimony given before a grand jury can be read by or discussed only with persons who have been designated under Rule 6(e). Neither FDA colleagues nor supervisors may be advised of the substance of grand jury activities unless they have been designated under Rule 6 (e).**

As with any pending investigation, there should be no comment whatsoever to the media or to the general public about the existence or activities of a grand jury. Even if there has already been speculation in the press about a grand jury or reports about it from witnesses called to testify before the grand jury (who are not bound by the rule of grand jury secrecy), no confirmation or other comment on the grand jury should be made.

Strict adherence to the rule of grand jury secrecy protects not only the integrity of the government's investigation and the validity of any indictment the grand jury might return, but the rights of the persons accused.

Compromising the 6(e) rule is a very serious matter and could result in dismissal of the charges, the suppression of valuable information, and/or a contempt citation against persons violating Rule 6(e).

DOJ and the U.S. Attorney may request FDA to provide investigative support to conduct interviews, accompany U.S. Marshals to seize evidence, and so on. Any person who is involved in this type of investigation will be given a 6(e) designation where these actions involve matters occurring before the grand jury.

6-5-13 - Preparation of Summary and Recommendation

See Exhibit 6-25 for a model format for the summary and recommendation memorandum and Exhibit 6-26 for an example of a food sanitation case. The Sample Index is an outline of the support samples related to the prosecution.

1. ***Sample Number, Product, Date Shipped***
   The order of the counts in an Information or Indictment is variable, but should be determined by the significance or seriousness of the violations, rather than the sequential order of the sample numbers or the date of sample collection. However, where all samples or schemes have the same degree of seriousness, list in descending chronological order (most recent offense in Count I, next most recent offense in

Count II, and so forth. The column headings may be changed to provide whatever information the district feels is significant. Beneath the sample number indicate the proposed count number. In cases where supporting samples are unnecessary, describe the scheme or violation and outline the elements of the offenses.

2. ***Citation Under Section 305 Of The FD&C Act***
List complete names and addresses of all persons issued Section 305 notices. Prepare brief, concise paragraphs explaining significant new evidence obtained since the Recommendation for Citation was submitted. Also include any changes in the status of responsible individuals or the firm that have occurred since the center approved the issuance of 305 notices or, in the case of direct reference cite authority, since the Section 305 notice issued. See the RPM section "Criminal Prosecution after Section 305 Notice".) If this is a recommendation without a Section 305 notice, prepare a brief paragraph explaining the facts, including identifying the basis of concurrence with this approach, for example, "**Ad Hoc** meeting."
3. ***Legal Status***
Prepare a brief paragraph describing the legal status of the firm as of the date of the S&R and at the time of the violations. If there has been a change in the legal status in the interim, furnish complete information concerning the change. As soon as the decision is made to recommend prosecution of a corporation, request certified copies of the Articles of Incorporation and the most recent Annual Corporate Registration. The annual corporate registration may list the current corporate officers at the date of filing. This request may be made in writing as shown in Exhibit 6-27 or in person so that the records are received in a form suitable for introduction into evidence (see Exhibit 6-28). If the Articles of Incorporation have been received before the recommendation has been submitted, so state in this section and enclose photocopies of the Articles with the recommendation. If they have not been received, include a statement that the Articles of Incorporation have been requested and photocopies will be submitted upon receipt.
When preparing photocopies of certified copies, the removal of any staples nullifies the certification. -- Caution the Legal Secretary/Technician about this.

If a corporation is dissolved, in most states it still legally exists for a period of time specified by the state in which it is incorporated and may be prosecuted during that period. In case of dissolution, submit copies of any notices thereof filed with the state and reports of any actions by the state on such dissolution.

4. ***Alleged Violation***
Prepare a summary of what the case is about. Include a statement on how the problem came to the attention of the agency. List the violations under this heading. In the event the proposed counts are numerous and the violations involve several different sections of a statute, you may use an outline or tabular form. Adulteration and misbranding charges should be charged in separate counts. In cases involving fraud, a detailed statement of all pertinent data (who, what, when, where, why, and how) concerning the scheme, from its conception through its perpetration, should be prepared. The following questions should be considered:
    a. When was the scheme initially implemented? By whom?
    b. What were its primary objectives?
    c. What were the methods by which it was implemented?
    d. Where was it put into operation and for how long?
    e. What was the nature of the scheme, the types of merchandise or service involved?
    f. Describe the magnitude, nature, and characteristics of the scheme (for example, number of units shipped, and amount of money involved).
    g. Describe the victims as to health, economic status, or other features.
    h. Identify for each proposed defendant or target any evidence reflecting that the offense was committed knowingly and willfully (intentionally).
    i. Identify potentially cooperative witnesses.
    j. Describe any noteworthy investigational problems encountered.
5. ***History***
State briefly the regulatory history of the firm and the individual defendants. Point out any cooperative work FDA has done with the state or other Federal agencies. Indicate any prior Federal action and any state legal action taken against the proposed defendants as well as any previous in rem actions.
6. ***Prior Notice***
As more fully explained in Chapter 10, when it is consistent with the public protection responsibilities of the agency and if a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations, it is FDA's policy to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. If voluntary correction is not achieved, documentation that adequate prior notice was provided strengthens the agency's position in enforcement actions by establishing that responsible individuals continued violating the law despite having been warned by the agency.

Indicate how and to whom prior notice was provided. If formal prior notice has not been given, indicate how the proposed defendants are aware of the consequences of their violative acts, or explain why prior notice is not necessary or appropriate in this situation.

7. ***Other Correspondence***
Provide reference to and copies of any correspondence that the agency (district, center, or other headquarters' unit) and state may have regarding matters subject to the recommended action.
8. ***Witnesses For Inspectional And Analytical Findings***
Arrange the samples (if any) by proposed count numbers listing the collecting investigator and the analysts. Identify the documentary and physical evidence associated with each witness and describe how this evidence was obtained, e.g., interview, inspection, surveillance, or other means. For a case with support samples, assign count numbers as in Exhibit 6-25.
9. ***Other Witnesses***
List the names, addresses, telephone numbers, and titles of any other known witnesses, including cooperating subjects of the investigation, FDA representatives from the center, and nongovernment expert witnesses with a summary of their anticipated testimony.
10. ***Recommendation***
List the persons being recommended for prosecution and the corresponding sample numbers (if any) or scheme that is the basis for prosecution. If any such persons have been previously convicted or are the subject of other legal action, include a paragraph stating the nature of the charge, the date the case was terminated, the disposition, the penalty imposed, the jurisdiction, and the case number (and an FDC, lead sample, or other FDA identifying numbers, if any). Indicate whether warnings were given and summarize the recommended defendant's response or corrective action. Indicate what harm has or can result from the criminal activity at issue, such as, type and total amount of loss, number and type of victims, and similar information. See also the RPM section on Prior Notice.
11. ***Permanent Abeyance of Samples or Non-Inclusion of Individuals***
If the district decides to place any of the samples listed in the Section 305 notice in permanent abeyance or to not include cited individuals as proposed defendants, the reasons for these decisions should be given in this section. Excluded samples should not be destroyed until the

termination of the action by plea or trial. If all samples and individuals listed in the Section 305 notice are included in the prosecution recommendation, this section may be omitted.

12. ***Sample Data***
This section is designed to furnish a brief summary of the available information in the file regarding each sample. Ordinarily, a criminal case should include more than one count and only in very unusual circumstances, which must be explained in the memorandum, will a one-count Information be referred to DOJ. Thoroughly discuss any potential problem areas with respect to the samples, such as a modification of official analytical methods during analysis, deviations from normal procedures in the collection of the samples, errors in the collection records, seals, analytical records which had to be corrected, or any inconsistencies between affidavits and records.
    a. Date lot shipped/received: For 301(a) or (d) violations, state the date the defendants shipped the lot or delivered it for shipment.For 301(k) violations, state the date the defendants received the lot, and for 301(c) violations state the date the lot was received and the date it was delivered or profferred for delivery. Occasionally, the receiving date in a 301(k) violation is not available. In such a case, the date of the offense is the day on which the investigator can testify that she or he saw the subject lot at the proposed defendant's premises. Occasionally, a 305 notice will issue with the date of shipment being the date furnished in an affidavit signed by the dealer, but subsequent investigation uncovers records indicating that the lot was actually shipped or delivered on another date. As long as the 305 notice stated "on or about" with respect to the date, this is acceptable. The correct date will be listed in the Information or Indictment, even if it differs from that listed in the Section 305 notice. Complete information regarding the conflicting dates should be furnished under the caption "Documentation of Interstate Commerce."
    b. Date lot sampled/by whom: If the sampling of the lot takes place over a period of several days, that should be stated here. In the case of a 301(k) violation, if the lot remains in the regular storage area for saleable goods, the Information or Indictment will indicate that it was held for sale between the date of receipt and the last day of the inspection. If the lot is moved to a quarantine area and it is clear that it is not to be sold, the day the product was moved (or destroyed, denatured, or embargoed) will be used in the Information or Indictment. In addition to the name of the collecting investigator, indicate where he or she is located at the time of the writing of the recommendation. If the investigator has transferred to another district, resigned, or retired, he or she should be contacted when the Information or Indictment is submitted to DOJ, advised that prosecution is pending, and requested to keep the district informed of his or her location so that the investigator can be contacted if the case goes to trial.
    c. Description of lot and sample size: The size of the lot should be listed and, in 301(k) sanitation cases, a brief description of the lot should be given. For example, the description should contain the statement that the investigator looked at (number of) bags, found urine on (number of) bags, (number of) bags were rodent gnawed, and should indicate whether filth was only on the exterior of the lot or on containers covered by other containers, whether or not the lot was received palletized, whether containers in the lot had been restacked by the firm, etc.
    d. Analysts: As with the collecting investigator, the current location of the analysts should be recorded and contact should be made with the analysts when the Information or Indictment is submitted to DOJ.
    e. Analytical methods: The method of analysis should be given. If there was any deviation from an official method, complete information concerning the modification and reasons therefore should be given. (In the analysis of official preparations, the method in the compendium should be followed.)
    f. Number of subs analyzed: If every sub has been analyzed, merely state "all." (It is incumbent upon the district's Compliance Branch to ensure that sufficient analytical work has been performed.)
    g. Analytical findings: The results of each analysis of the product should be listed. If the problems which were encountered necessitated additional work, or deviation in or from an official method such as new methodology or analysis to resolve discrepancies in analytical results, such matters should be disclosed and discussed. In cases involving filth in foods, the analytical findings should be broken into two groups; those demonstrating actual contamination in the product [402(a)(3)] and those demonstrating 402(a)(4) conditions. The results regarding the findings of actual product contamination should be summarized basically as follows:

        Section 402(a)(3) Verification
        Subs _____, _____, and _____ - gnawed - incisor marks - confirmed.

        Subs _____, _____, and _____ - contained rat or mouse excreta or hair - confirmed.

        Sub _____ - insects (identities, if possible)

        Section 402(a)(4) Verification
        If there is substantial 402(a)(3) evidence, the subsamples collected from the surface and proximity of the lot need only be briefly summarized, covering each type of 402(a)(4) filth present. This includes rat or mouse excreta, rodent urine, and rodent nesting material as being confirmed or identified.

        If the proposed charges differ from the data listed under "Analytical Findings" or the charge sheet that accompanied the 305 notice, the reasons for the differences should be discussed.
    h. Section 702(B) Portion: In any case involving analytical work, a portion of the sample usually should be available for the defendant, should he or she request it. Verify whether the section 702(b) sample portion is available, and note the amount available. If a 702 (b) portion does not exist, this fact should be conspicuously noted and an explanation provided.

        Some exceptions to the requirement for 702(b) portions are codified at 21 CFR 2.10. If all subs have been analyzed, there is a presumptive 702(b) concern which should be addressed.

        NOTE: Filth exhibits do not require a 702(b) portion.
    i. Seizure: If the lot forming the basis for a proposed count was seized, list the case number and the FDC number and state the disposition of the seizure.
    j. Documentation of interstate commerce: State the name and title of individuals signing dealer statements and affidavits, the name and address of the firm for which they work, and list the documents furnished, including information such as purchase order, invoice, freight bill, and bill of lading numbers, and the dates they were issued. Interstate commerce witnesses are sometimes called on to testify and supply the original documents in the event the case goes to trial.
    k. Remarks: This section should contain detailed information concerning any potential problem areas or weaknesses in the case not covered in the description of the individual counts. Include the ages of the proposed defendants and, if known, any physical problems they may have. Also, indicate that OCI was contacted regarding the case. Finally, state why prosecution is the action of choice.

6-5-14 - Submission of Summary and Recommendation Documents

The summary and recommendation (S&R) documents are submitted to the center, DCMO and OCC, depending upon the instructions described in the applicable case procedure, "Criminal Prosecution after Section 305 Notice", "Criminal Prosecution Without Section 305 Notice", or "Referrals for Criminal Investigation."

1. ***Prosecutions Requiring Center Approval***
    a. Submit the S&R (prepared as described in "Preparation of Summary and Recommendation") and the supporting documents listed below by uploading them into CMS.
        i. Section 305 Notice and Charge Sheet
        ii. Record of Section 305 meeting and any documents presented at the meeting
        iii. Written answer to the Section 305 notice (if meeting was not held)
        iv. Any correspondence or memoranda of telephone conversations with proposed defendants since the Citation Recommendation was submitted.
        v. Guaranty (if applicable)
        vi. Articles of Incorporation (Photocopy can be submitted in CMS and district will maintain the original. DO NOT HOLE PUNCH the original document).

        Centers should upload their approval memo into CMS.

        NOTE: If the recommendation meets the circumstances outlined in "Processing a Summary and Recommendation" and does not require further review by the center, submit the S&R and supporting documents to DCMO as described in "Direct Reference Prosecutions" below.

2. ***Direct Reference Prosecutions***
    The S&R prepared as described in "Preparation of Summary and Recommendation" should be uploaded into CMS. The district should transfer the case to DCMO by changing the current owner to DCMO pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DCMO designated to receive notification when ownership of a case has changed to that office. The S&R should contain the supporting documents listed above.

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