Guidance for FDA Staff

Civil Money Penalty Policy

Draft Guidance – Not for Implementation

This guidance document is being distributed for comment purposes only.
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Compliance

Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. 99D-1273 , Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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APPLICATION OF THE SAFE MEDICAL DEVICES ACT
CIVIL MONEY PENALTY POLICY

PURPOSE:

This document is addressed to all FDA Regional and District Directors for the purpose of advising field personnel of this new guidance policy when pursuing potential Civil Money Penalty (CMP) recommendations under the Safe Medical Devices Act of 1990 (SMDA).

This guidance document represents the Agency's current thinking on CMP recommendations under the SMDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. FDA may use an alternative approach if such approach satisfies the requirements of the applicable statute, regulations, or both.

BACKGROUND:

The SMDA authorized FDA to impose CMP actions under Section 303(f) for all violations of the Federal Food, Drug and Cosmetic Act (the Act), involving medical devices except:

- Good Manufacturing Practice (GMP) and Medical Device Report (MDR) violations unless they constitute a significant or knowing departure from such requirements or a risk to public health,
- Filth violations in devices that are not otherwise defective, and
- Minor violations for tracking and reports of corrections.

Thus, FDA has considerable latitude when applying CMP to violations involving devices. CMP cases should serve to eliminate the profit from violative activity and/or to provide non-compliant firms with the financial incentive to correct violations. The financial incentive is created by a defendant's desire to minimize the number of violations and, when appropriate, by FDA's decision to allow a defendant to apply a portion of the CMP to offset the cost of correction.

This policy outlines the use of CMP for GMP and premarket notification [510(k)] violations, for chronic and repeat violators, and for less significant violations. It also discusses the relationship between CMP and seizure or injunction.

GMP:

CMP actions should be considered for those situations in which a firm continues to violate the GMP regulations, there is a reasonable probability that the firm will likely produce nonconforming and/or defective finished devices, and seizure or injunction is not appropriate or necessary to bring about corrective action.

Prior warning of violative conduct must be documented in accordance with Agency policy. In some circumstances, the initiation of a CMP proceeding, coupled with a stated process for abating all or part of the assessed penalty for prompt and complete corrective action, may provide an incentive for the firm to spend money on correction rather than CMP.

The District should consider a CMP action for Situation 1 GMP deficiencies which are the most serious (see C.P. 7382.830), after prior warning, involving the same or closely related GMP deficiency observations. The prior warning should include notice that one of the regulatory actions that may be taken without further notice includes CMP. When the decision is made to proceed with CMP, the District Office should send the defendant(s) a letter with the complaint attached. The letter should state that FDA is immediately filing the attached complaint which officially initiates CMP proceedings against the responsible persons. The complaint should identify: 1) the documented GMP violations, 2) the reasons that the person(s) is (are) responsible for the violations, 3) the penalty amount FDA is seeking against each person, and 4) the procedures for answering the complaint and requesting a hearing. The letter will also include a statement that when a small business, as defined by the U.S. Small Business Administration (see table of size standards), properly documents that funds have been spent on corrections, these funds will offset the penalty FDA is seeking.

The investigator must establish the point at which correction should have been complete ("compliance date") following the previous violative GMP inspection. This could be the date of the Warning Letter or other prior notice, the date of the firm's response to the prior notice, or a date established in the firm's response as to when it plans to have all corrections completed. If the firm has responded and provided a timeframe for correction, the District should consider using that timeframe, if it is reasonable, to establish the compliance date. If there is no response, the compliance date should be the date of the Warning Letter or the date other prior notice was provided to the firm.

Once the compliance date has been established, the investigator must then document shipments of product manufactured under poor GMP from that time forward. This documentation will then

serve as one basis for determining the appropriate penalty from the "SMDA Civil Money Penalty Fee Matrix," provided that the District Office has established through the "SMDA Civil Money Penalty Decision Tree" that CMP is the action of choice. The above documentation must be complete before the case recommendation is submitted to CDRH for review.

Prior concurrence from CDRH, the Office of Enforcement (OE), and the Office of Chief Counsel (OCC) is required before issuing the letter, with the complaint attached, to the responsible person. Once approved by CDRH, OE and OCC, the letter, with the complaint attached, is then issued to the firm and the complaint is filed in the Dockets Management Branch.

PREMARKET NOTIFICATION [Section 510(k)]:

CMP actions may also be appropriate for situations in which a firm markets a device without the required clearance under Section 510(k) of the Act. Prior warning of this violative activity must be documented in accordance with Agency policy unless the violations represent a danger to health or are egregious in nature.

As in the GMP context, the potential for a CMP combined with a stated process for abating all or part of the assessed amount for corrective action, may provide sufficient incentive for the firm to spend funds to obtain 510(k) clearance.

Unless exempted, 510(k) clearance is required, in accordance with 21 CFR 807.81.

In the case of a modified product, the firm may have 510(k) clearance for a prior model of the device in question, but not for the modified device. Occasionally, firms have claimed difficulty in ascertaining what constitutes a significant change and have erred in favor of not filing 510(k) submissions for such changes. In some instances, however, FDA has later determined that 510(k) submissions were, in fact, necessary. In all instances, firms are free to seek CDRH guidance on the need to file a 510(k).

In January 1997, CDRH published **a** final guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device." A draft form of this document was available in 1994, and was redrafted in 1996. This document incorporates considerable industry input and has been very useful for both the FDA and the industry. Nonetheless, until there has been more experience with the document, CMP cases based on failure to submit a 510(k) for a modified product should only be submitted when the product change is clearly significant. Collect and review any documentation of the basis of the manufacturer’s decision not to submit a 510(k) for the modified device.

As discussed in the "GMP" section above, the investigator must use the compliance date as the starting point for documenting violative shipments. That date could be the date of receipt of the Warning Letter or other form of prior notice, the date of the firm's response to the prior notice, or, if it is reasonable, a date in which the firm claims it will have 510(k) clearance.

Once the compliance date has been established, the investigator must document product shipments from that point forward. This documentation will serve as one basis for determining the appropriate penalty amount in accordance with the "SMDA Civil Money Penalty Fee Matrix," provided that the District Office has established through the "SMDA Civil Money Penalty Decision Tree" that CMP is the action of choice. CMP may be used even when the firm ultimately obtained 510(k) clearance after receipt of Agency prior notice if the firm shipped articles after prior notice but before obtaining the clearance(s).

Note that CMP cases involving the lack of 510(k) clearance are not subject to the procedures outlined under, "Less Significant Violations."

CHRONIC/REPEAT VIOLATOR:

Persons that continue to violate the law, e.g., fail to conform to GMP, fail to submit premarket notification, commercialize an investigational device, etc., may fit the definition of "chronic violator" or "repeat violator." Chronic violators remain "out of compliance" for at least two inspections. The second and subsequent inspections find that the person has not corrected the violations, either because the person has not attempted to correct or because the attempts have fallen significantly short of the mark. Persons that are repeat violators are those that fluctuate between being "out of compliance" and "in compliance" from one inspection to the next.

Chronic and repeat violators of GMP may be good candidates for CMP action. Following violative GMP inspections, repeat violators characteristically initiate minimal correction which barely avoids classifying the inspection as Situation 1 (see C.P. 7382.830), only to return to a Situation 1 status at a later date. Chronic and repeat violators for the failure to obtain appropriate 510(k) clearance may also be good candidates for CMP action.

SEIZURES/INJUNCTIONS NOT APPROPRIATE:

CMP may be appropriate in situations where seizures or injunctions were not the action of choice (provided evidence of the violation is clear) or where it has been determined that seizure or injunction is simply not appropriate (i.e. insufficient product available for seizure; evidence too old for injunction).

CMP may be considered for promotion and advertising violations, failure of sponsors to meet IDE reporting requirements, or failure of clinical investigators to submit completed case reports. These are all situations where seizure or injunction would not normally be the action of choice.

PROBLEMS WITH LOW RISK DEVICES:

Use of CMP is consistent with CDRH's efforts to use a risk-based approach to determine the kinds of regulatory actions that it should take. This means that for cases where the Center has in the past taken seizure or injunction action for low risk devices, the Center now has available an alternative legal action (CMP) for such situations.

Additionally, situations which in the past were not efficient uses of the seizure or injunction remedy will now be considered CMP candidates, e.g., violative situations involving low risk devices. Violative situations involving low risk devices may present situations where initiation of a CMP is more appropriate than other regulatory action.

LESS SIGNIFICANT VIOLATIONS:

With a few exceptions, the SMDA enables FDA to assess CMPs for less significant violations, and the Agency intends to more actively use this enforcement action for such a purpose. For example, for a violation with "low significance" (see fee matrix) there would be a maximum initial CMP of $50,000.00, per defendant and for each case.

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SAFE MEDICAL DEVICES ACT CIVIL MONEY PENALTY DECISION TREE

GENERAL PHILOSOPHY

The Safe Medical Devices Act of 1990 (SMDA) added civil money penalty (CMP) authority as a supplement to the existing statutory remedies of seizure, injunction, and prosecution, primarily to "take the profit out of noncompliance."

CMP is considered to be a remedial action, not punitive. This means it is designed to influence future conduct of the affected firm and/or other firms that are similarly situated, either directly, by affecting current violative conduct, or indirectly, by serving to deter future violative conduct.

When the monies spent on corrective actions will be deducted from the fine imposed, CMP action can also provide non-compliant firms with a financial incentive to come into compliance. This was authorized by a Presidential Memorandum, dated April 21, 1995, and the Small Business Regulatory Enforcement Fairness Act of 1996. In these cases, even if the firm pays a sharply reduced fine, the remedial goal of the CMP action will have been accomplished if the firm successfully and promptly brings itself into compliance.

Pursuant to the SMDA, CMP cases that have not been settled are in the first instance resolved by administrative hearings, if the individual or company requests it by filing an answer. Hearings are held before an Administrative Law Judge in accordance with procedures contained in 21 CFR Part 17. Appeals can be heard by the Health and Human Services Departmental Appeals Board and subsequently by a United States Circuit Court of Appeals, if needed. Evidence and testimony developed for administrative hearings must be prepared as carefully and as thoroughly as if the case were being tried in federal court. Companies that wish to avoid hearings may resolve the dispute by entering into consent agreements.

BACKGROUND

On April 7, 1994, the Center for Devices and Radiological Health (CDRH) released a draft CMP Policy which outlined the criteria and procedures for implementing the CMP provisions of the SMDA. This policy provided examples of situations for the application of CMP.

It also specified the factors that FDA must consider when imposing such penalties. Those factors are outlined in Section 303(f)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and include, but are not limited to: gravity of the violations, history of past violations, ability to pay, and the effect of the penalty on the ability to continue to conduct business.

On July 27, 1995, the final Civil Money Penalty Rule governing procedures to be used in CMP matters was published in the Federal Register.

After reviewing several CMP recommendations, CDRH recognized the need to provide additional guidance for the consideration and development of these types of cases. The following three documents supersede the April 1994 CDRH draft CMP policy:

1. Application of the SMDA Civil Money Penalty Policy
2. SMDA Civil Money Penalty Decision Tree
3. SMDA Civil Money Penalty Fee Matrix

DECISION TREE PROCESS

The Decision Tree is designed to assist the Office of Regulatory Affairs (ORA) (Districts and the Division of Compliance Management Operations (DCMO)) and the Center in determining whether the evidence and information collected justifies pursuing a CMP case. It is NOT an all-inclusive list of every issue that should be considered, but rather is a series of questions to guide your decision whether to pursue CMP or other available regulatory options.

The Decision Tree reflects that CMP may be considered in cases where:

- In general:
    - Other regulatory action is NOT appropriate,
    - Prior warning has been given,
    - FDA policy is clear; and
- Statutory factors in Section 303(f) support the case.

At the bottom of the tree, there are examples of situations in which CMP may be particularly appropriate. However, note that this is not an all-inclusive list.

Please go through each of the questions in the tree (attachment #1). Each question covers an issue that may affect your case. The answers will provide you with an indication of some of the strengths and weaknesses of your case and should help you decide whether CMP is the appropriate action of choice.

1. Suitability of Other Regulatory Options

First, determine whether regulatory action other than CMP is necessary to address the violations. Current violations warrant consideration of seizure or injunction. (A combination of CMP with

seizure or injunction should be considered only on rare occasions and only for egregious or flagrant violations).

If other civil action is not deemed appropriate, consider whether prosecution is appropriate. CMP and prosecution will not be initiated for the same violative conduct. Should neither seizure, injunction, nor prosecution be appropriate, you may want to consider CMP. CMP may be used for both past violations that have since been corrected as well as for current or continuing violations.

Note that CMP action may be appropriate in situations in which all of the violations have been corrected. For example, CMP could be used for a firm that continued to violate the law for a period of time before coming into compliance. In this instance, CMP would eliminate or reduce the profit derived from the violative activity; however, in setting a penalty amount, please bear in mind that in some cases violators may deem it advantageous to distribute devices even though no short term profits are realized.

2. Prior Warning

If other regulatory action is not appropriate, consider whether FDA has notified the firm or individual of a violation of the Act. Examples of prior warning include:

a. Warning Letter, civil suit, administrative action, or other regulatory correspondence.

b. Notification by state, municipal, or other federal agencies involving the same or similar violations.

c. FDA-483 (List of Inspectional Observations) provided by an FDA investigator at the conclusion of an inspection.

d. Discussion of objectionable conditions with a responsible individual of the firm and an FDA investigator that have been documented in the establishment inspection report.

e. Verbal notification from Agency officials to a firm's top management, e.g., in meetings or telephone conversations confirmed in writing.

f. Written or oral advisory communication by FDA Center personnel involving critical scientific issues.

g. Industry meetings during which pertinent violations are discussed if attendance by a firm's representatives is documented.

Only in rare and compelling cases should a CMP be initiated without prior warning. Consult DCMO (HFC-210) if you have questions regarding the prior warning policy.

3. Clarity of FDA Policy

If there has been prior warning, determine whether the Agency's expectation (policy) is clear regarding the regulatory requirements affecting the potential defendants. For example:

- Is there a regulation covering the subject;
- Is there an industry letter from FDA or other official FDA document available to the industry;
- Have these communications, in whatever form, provided industry with a clear description of FDA policy; or
- Has the Agency taken prior enforcement action for the same or similar conduct.

The key is whether a neutral person would say that industry had or should have had a clear understanding of FDA's requirements.

4. Statutory Factors

If the policy is clear, consider the statutory factors under section 303(f)(3)(B) of the Act. FDA is required to consider the following statutory factors in determining the amount of the CMP in each case: the nature, circumstances, extent, and gravity of the violations, and with respect to the violator, the ability to pay, the effect on the ability to continue to do business, any history of such prior violations, the degree of culpability, and such other matters as justice may require. The recommendation should contain a written assessment by the District of each of these factors.

The evaluative factors listed below are intended to assist your decision when making a penalty assessment and to help provide more consistent assessments among different Agency components and defendants so that like cases will, to the extent practicable, be treated in a like manner. However, the discussion of the factors listed below cannot be, and is not intended to be, exhaustive or iron-clad. Evaluating an appropriate penalty and human behavior are inherently subjective exercises that preclude a complete checklist and precise calculations.

A description of each factor, including specific questions to consider in evaluating each factor, follows.

Nature of the violations refers to a general evaluation of the type and seriousness of statutory or regulatory violation(s) considered in the abstract, without regard to the facts of a particular case. The general seriousness of the violation refers to the relationship of the type of violation to the different purposes of the Act.

Violations of laws and rules that relate to the Act's core purposes and the Agency's mission, e.g., the premarket approval and clearance provisions and provisions that bear materially on the safety and effectiveness of the product would be very serious; violations of misbranding provisions, e.g., those prohibiting false or misleading claims, may be in a mid-range of severity. Violations of provisions requiring that labels declare the identity of the manufacturer (unless the omissions were part of a plan to avoid detection) may be evaluated "low." The seriousness of GMP violations will vary. Thus, a violation of a record keeping requirement might be "low," whereas a failure to sterilize a device would probably be "high."

Circumstances of the violations refers to the context in which the violations occur and to facts extrinsic to the legal elements of the violations themselves. The circumstances of violations may include both mitigating and aggravating factors. Examples of facts to be considered in this category include the clarity and number of the prior warnings; the clarity of applicable statutes, regulations, or policies; and whether the violations were of an obvious nature.

Extent of the violations refers to the number and variety of documented violations and the length of time during which the violations continued. Although you may only use the number of shipments to calculate the initial penalty assessment (see "Maximum Fees per case", below), you may consider the number of devices included within each shipment to evaluate the extent of the violations.

Gravity of the violations refers to the consequences, actual and potential, of the violations. Consider, for example, whether any patients or users were harmed or placed at risk of harm by the violation; the classification of the device (generally, violations involving class III devices will increase the gravity of the offense); whether the defendants benefited from the violation (e.g., by generating sales, maintaining market position, or creating an early market niche or other advantage); and the amount of Agency or other public resources that were needed to investigate and rectify the violations.

Ability to Pay - In evaluating this factor, consider the size of the firm, including factors such as revenues (sales); assets, including accounts receivable; past and projected liabilities; and the financial position of any individual defendants. Does the firm have, at a minimum, assets that would permit it to pay the fine over time?

In assessing fines for small businesses, you must take into account the money spent to correct the violations for which the fines are being sought. (See Presidential Memorandum 4/21/95 (60 FR 20621) and Small Business Regulatory Enforcement Fairness Act of 1996.)

The penalties should be modified or waived only if the firm made a good faith, prompt effort to comply; compliance has been achieved; if there was no significant threat to the public health; and if the monies spent have been carefully, thoroughly, and specifically documented for each compliance

activity. Where appropriate, the District and CDRH may seek underlying records to substantiate the claimed expenses. In this regard, the district may consider requesting the firm's signed records including the most recent tax filing for purposes of determining the ability to pay.

The term "small business" is defined specifically with regard to most device manufacturers, categorized by device industry, as a company, including its affiliates, with fewer than 500 employees. Examples of specific industries meeting this definition include, Surgical and Medical Instruments and Apparatus; Dental Equipment and Supplies; X-Ray Apparatus and Tubes and Related Irradiation Apparatus, Ophthalmic Goods; Orthopedic, Prosthetic and Surgical Appliances and Supplies; Optical Instruments and Lenses; and Electromedical and Electrotherapeutic Apparatus. See U.S. Small Business Administration, Table of Size Standards, (March 1, 1996).

However, be aware that there may be exceptions to the rule. For example, Electronic Computers, Computer Storage, and Computer Peripheral Equipment N.E.C. and Primary Batteries are device industries where small business is considered to have fewer than 1,000 employees.

Check the Table of Size Standards for other appropriate device industry categories. If necessary, you may contact the Office of Size Standards, U.S. Small Business Administration, Washington D.C. Telephone: (202) 205-6618.

NOTE: Prior to evaluating the ability to pay and whether the firm can continue to do business, the two financial factors, the Districts should assure themselves that all of the other statutory factors support the case. If for some reason there is little or no financial information available on either a firm or responsible individual(s) and all of the other statutory factors support the case, then the District should consult with the Office of Enforcement (OE) to obtain further information and submit the recommendation.

To assist the Districts in addressing the two financial factors, OE's Division of Compliance Policy (DCP) will provide financial information concerning both firms and individuals. All such requests should be directed to Eileen Rhoads (HFC-230) via electronic mail or facsimile (fax 301-827-0482, phone 301-827-0928).

By using Lexis/Nexis research computer software, DCP will search available databases for financial and other relevant information which may include, but not be limited to, the following:
corporate records (state and date of incorporation, history and officers); background on corporate officers and executives including salaries; number of employees and employment growth; related firms (parent or subsidiaries); marketed products; annual sales; growth rate; net income; market share; credit rating; assets (cash, securities, receivables, inventories, raw material and equipment); liabilities (debts, taxes, mortgages); cash flow and earnings statements; stock price and outstanding shares. DCP may also be able to obtain documents filed with the Securities and Exchange

Commission (SEC); annual reports; mergers and takeovers; prospectuses; property records; judgments, settlements and liens; verdict reports (facts of the case, jury's response, and any damage awards); and bankruptcy filings.

Effect on Continued Business - In evaluating this factor, the most important issue is the relationship between the penalty FDA is seeking and its effect on the firm's ability to remain in business (i.e., pay salaries and rent, purchase raw materials and equipment, etc.) after payment of the penalty. To the extent we can determine, what is the firm's financial position? Are there any indicators that the firm may be in bankruptcy or have judgments against it? If there is no money to pay the fine, then consider other regulatory actions.

If possible, obtain any information related to the financial status of the firm or most responsible individual(s) during the inspection. For example, the gross annual sales volume, the kind and number of devices manufactured and shipped within representative months or quarters, the unit sale prices, the corporate annual report, the names and addresses of any parent or marketing firms and subsidiaries, and legal suits or judgments against the firm or individual(s).

History of prior violations refers to prior conduct of the person that is similar in nature to the violations in the current case; you may consider conduct as similar even if it does not implicate the identical law or regulation. You should also consider the number of previous similar violations, the similarity of the previous violations to those in the case under review, the temporal proximity of the previous violations to the current violations, the method by which the previous violations were brought to the person's attention (e.g., by a Form FDA-483, Warning Letter, meeting, judicial action), and the person's responsiveness and attitude in correcting the previous violations (e.g., whether the violations were corrected willingly, promptly, and completely).

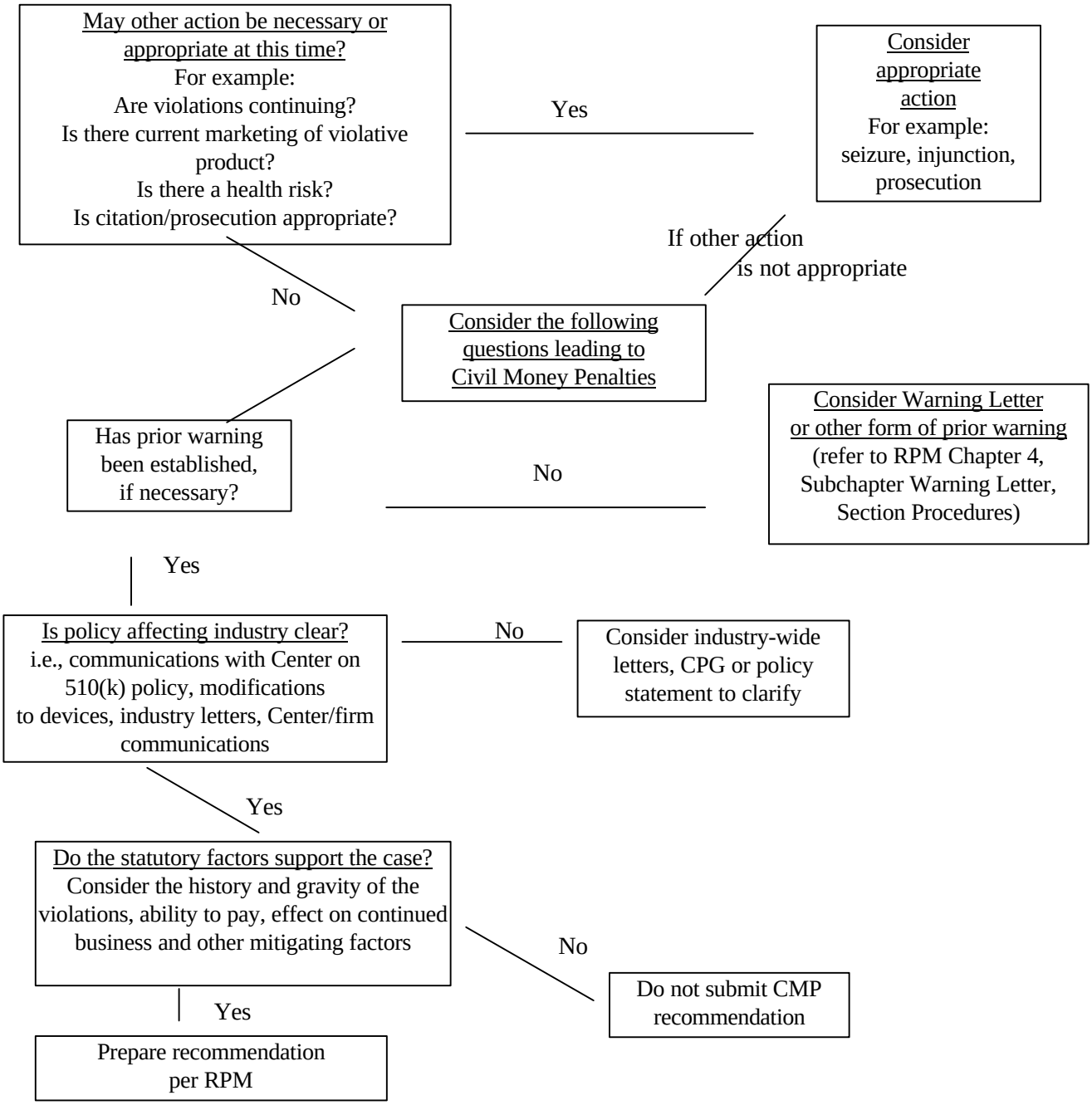
Degree of culpability refers to the level of blameworthiness. Consider, for example, whether the violations were intentional, reckless, careless, or inadvertent; whether the persons were obstructive or cooperative during the investigation and following notification; whether the violations involved were condoned by many actors or high level corporate officials; whether, upon learning of the violation, the person took timely action to correct the violation, eliminate or reduce the risk that the instant violation would cause future harm, and made restitution to any parties harmed by the violative conduct. You should also consider whether, within a reasonably prompt time after becoming aware of the offense -- and before and without knowledge of the commencement of a
formal investigation of that violation -- the person disclosed the violation to FDA; and whether the violation occurred despite the defendant's implementation of a program designed to prevent and detect violations of law.

Other factors as justice may require is a catch-all category that permits consideration of any fact, whether aggravating or mitigating, that reasonably bears upon the evaluation of a penalty assessment. Among other factors, you may consider the factual and legal strength of the government's case, the availability and credibility of witnesses, and the amount of resources that would be required to adjudicate the case.

TIMING

A case recommendation should be submitted within 6 months of either FDA's discovery of the violations or their correction.

SMDA CIVIL MONEY PENALTY (CMP) DECISION TREE



Applying civil money penalties	Consider some of the following examples of where CMPs can apply: second inspection with documented Situation I GMP or chronic violations, failure to 510(k), or promotion/advertising violations
Time consideration	Submit the case within six months of discovery or corrections of violations.

SAFE MEDICAL DEVICES ACT CIVIL MONEY PENALTY FEE MATRIX

BACKGROUND:

FDA is authorized to impose CMP administratively under certain provisions outlined in the Safe Medical Devices Act (SMDA) of 1990. Since that time, FDA has completed administrative CMP cases that have resulted in payment of monetary penalties to the U.S. Treasury.

The CMP regulation (21 CFR part 17) became effective in August 1995, and FDA intends to use this enforcement tool more actively to address certain types of violative situations. FDA has determined that to help ensure consistency in the assessment of CMP, specific guidance for calculating the penalty amounts that the Agency will pursue is desirable.

FEE MATRIX OVERVIEW:

The fee matrix is designed to assist the Office of Regulatory Affairs (ORA) and CDRH in determining the initial penalty amount to assess. The schedule covers the statutory factors that FDA is required under SMDA to evaluate in determining whether a CMP case is appropriate. (See Section 303(f) of the Act).

The fee matrix is a chart that attempts to calculate the statutory factors by assessing the significance of the violation. Significance is initially measured in terms of a low or high rating for each factor. The evaluation is arrived at by adding the scores for each of the statutory factors in the left column. If, in considering each of those factors, the overall violation significance is low, then the penalty is calculated by multiplying the number of shipments/violations by $5,000. Likewise, for a violation significance of medium or high, the total penalty would be $10,000 or $15,000, respectively, multiplied by the number of shipments/violations.

A shipment is considered to be a quantity of devices shipped to a consignee at one time, usually evidenced by an invoice and related shipping documents. For example: 10 pacemakers to USA Hospital on 1/2/97 is equal to 1 (one) shipment, NOT 10.

In situations where there are no shipments, such as clinical studies, a violation is each occurrence of violative conduct. For example, failure of a sponsor to submit 10 required reports to the FDA would be 10 violations.

This guidance for assessing fees will be re-evaluated after the Agency obtains some experience.

STATUTORY FACTORS: ***SEE SMDA CMP DECISION TREE, "Decision Tree Process,"

section 4, "Statutory Factors."

Points are assigned for the significance of each of the statutory factors. The weights given to the extent, gravity, and prior history factors are twice those for the other six factors because those factors attempt to measure overall seriousness of the violations. The point total for all factors can then be used to place the overall violation significance in one of the defined categories. The point breakdowns are as follows:

	Low	High
Nature	1	3
Circumstances	1	3
Extent	2	6
Gravity	2	6
Ability to Pay	1	3
Effect on Continued Business	1	3
History of Prior Violations	2	6
Degree of Culpability	1	3
Other Factors as Justice May Require	1	3
Totals	12	36

Violation Significance Point Ranges:

Low	12 - 19
Medium	20 – 28
High	29 and above

MAXIMUM FEES PER CASE:

For the low, medium, and high evaluations, the dollar figure is set at $5,000, $10,000, and $15,000, respectively, per shipment/violation. This suggested dollar figure is then multiplied by the number
of shipments/violations to calculate an initial penalty. The maximum initial penalty per defendant for each case is $50,000 for low, $350,000 for medium, and $1,000,000 for high.

The initial penalty may be adjusted if the defendants provide documented, reliable business information, particularly with respect to the ability to pay and/or the ability to continue in business once a penalty is paid. The amount of the penalty that the defendant ultimately pays may also be adjusted through negotiation or, if the case goes to a hearing, by order of the Administrative Law Judge.

Note also that in assessing fines for small businesses, FDA will take into account the money spent to correct the violations for which the fines are being sought. (See Presidential Memorandum April 21, 1995 (60 FR 20621) and Small Business Regulatory Enforcement Fairness Act of 1996). The penalties should be modified or waived only if the firm made a good faith prompt effort to comply; if compliance was achieved; if there was no significant threat to the public health; and if the monies spent have been carefully, thoroughly, and specifically documented for each compliance activity. Where appropriate, the District and CDRH may seek underlying records to substantiate the claimed expenses.

The term "small business" is defined specifically with regard to most device manufacturers, categorized by device industry, as a company, including its affiliates, with fewer than 500 employees. Examples of specific industries meeting this definition include, Surgical and Medical Instruments and Apparatus; Dental Equipment and Supplies; X-Ray Apparatus and Tubes and Related Irradiation Apparatus, Ophthalmic Goods; Orthopedic, Prosthetic and Surgical Appliances and Supplies; Optical Instruments and Lenses; and Electomedical and Electrotherapeutic Apparatus. See U.S. Small Business Administration, Table of Size Standards, (March 1, 1996).

However, be aware that there may be exceptions to the rule. For example, Electronic Computers, Computer Storage, and Computer Peripheral Equipment N.E.C. and Primary Batteries are device industries where small business is considered to have fewer than 1,000 employees.

Check the Table of Size Standards for other appropriate device industry categories. If necessary, you may contact the Office of Size Standards, U.S. Small Business Administration, Washington D.C. Telephone: (202)-205-6618.

When the Office of Chief Counsel (OCC) is involved in the mitigation of the CMP or in settlement negotiations and needs additional information from FDA personnel, the OCC staff attorney should contact the appropriate field, Center and OE representatives.