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November 27, 2006

VIA ELECTRONIC MAIL AND FEDERAL EXPRESS

dea.diversion.policy@usdoj.gov

Deputy Administrator
Drug Enforcement Administration Headquarters
2401 Jefferson Davis Highway
Alexandria VA 22301
ATTN: DEA Federal Register Representative

Re: Retail Sales of Scheduled Listed Chemical Products (SLCP's) and Self-Certification of Regulated Sellers of SLCP's; 21 CFR, Part 1314 (Docket No. DEA-2911)

Dear Deputy Administrator,

The Food Marketing Institute (FMI)[1] is pleased to respond to the Drug Enforcement Administration's (DEA's) request for comments on the Agency's interim final rule on the retail sale of scheduled listed chemical products (SLCP's) and the self-certification of regulated sellers of SLCP's. 71 Fed. Reg. 56008 (Sept. 26, 2006) (hereinafter "the interim final rule"). DEA promulgated the interim final rule pursuant to the Combat Methamphetamine Epidemic Act (CMEA), which was signed into law in April, 2006 and which places significant operational requirements on retailers of SLCP's as of September 30, 2006.

At the outset, we note that the retail food industry recognizes the substantial detrimental impact that the methamphetamine epidemic currently has on the United States. FMI and its members are committed to taking all necessary steps to comply with the CMEA and to assist in the reduction of SLCP abuse. Indeed, many FMI members voluntarily implemented measures now required by the CMEA before the Act was passed.

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[1] FMI conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

With respect to the regulations themselves, we note that DEA was required to promulgate challenging rules in a very short time frame. We appreciate the outreach that DEA has performed and continues to provide to help the retail community achieve the greatest possible level of compliance as quickly as possible. As a result of this ongoing cooperative partnership between our industry and DEA, great strides have been made by retail stores to achieve a high degree of compliance quickly.

Nonetheless, as DEA promulgated the interim final rule without the benefit of a public comment period, we respectively request that the Agency include the changes discussed below in the final rule. We particularly call your attention to the changes recommended to Section 1314.30(a)(2), which requires retailers who choose to satisfy the statutory logbook requirement with paper logbooks, to maintain them in bound form. The CMEA has no such requirement, so the DEA interim final rule is beyond the scope of the Agency's statutory authority. Moreover, DEA has provided no rationale for requiring paper logbooks to be bound and has failed to consider the considerable burden that the requirement places on regulated sellers. DEA should remove the requirement entirely or replace it with a less burdensome alternative discussed more fully below.

A. Restrictions on Sales Quantity (21 CFR Section 1314.20)

The CMEA institutes significant new restrictions on the quantity of SLCP's that may be purchased or sold in specific time periods. Specifically, the CMEA prohibits retailers from selling SLCP's that contain more than 3.6 grams of a scheduled listed chemical base per day to a consumer, regardless of the number of transactions. 21 USC 830(d)(1). In addition, and in a separate section of the Controlled Substances Act, as amended by the CMEA, the statute prohibits individuals from knowingly or intentionally purchasing more than 9 grams of a scheduled listed chemical base in a 30 day time period.[2] 21 USC 844(a).

The preamble references these requirements[3] and Section 1314.20 of the interim final rule codifies the sales limitation, stating that retailers are prohibited from selling more than 3.6 grams of SLCP base in a single calendar day, regardless of the number of transactions.[4] In addition to the foregoing, however, the CMEA includes significant language regarding retailers' liability with respect to the sales limitation. In particular, the CMEA states that the retailer is not required to consult the logbook in order to determine whether or not the sales

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[2] We agree with the interpretation of the time periods that DEA set forth in the preamble. Namely, the daily sales limit is interpreted in reference to each calendar day and the 30 day purchase limitation is evaluated on a rolling 30-day period. 71 Fed. Reg. at 56011. We encourage DEA to carry these determinations forward into the final rule or the preamble thereto.

[3] Although the preamble is mostly consistent in distinguishing between the purchase and the sales limit, we note that in the discussion of the 30-day limitation period, the Agency refers to the "30-day sales limit." We encourage DEA to ensure that all references to the 30-day limit in the preamble and final rule denote the 30-day *purchase* limit. 71 Fed. Reg. at 56011.

[4] We agree with DEA's decision to codify the 30 day purchase limitation in a separate part of the regulations. Including the purchase limitation in Part 1314 would only cause confusion.

limit has been exceeded. DEA should codify the full breadth of the statutory requirements in the final regulations and add the following sentence to Section 1314.20(a):

> A regulated seller is not required to consult the logbook to determine whether or not the sales limit has been met or exceeded.

DEA is not required to promulgate any regulations with respect to the sales limitation – it is a creature of statute – however, if the Agency is going to codify the limitation, the Agency should also codify the statutory language reflecting the scope of the limitation. In the absence of such codification, the regulations present a misleading perspective on the sales limitation.

B. Recordkeeping for Retail Transactions (21 CFR Section 1314.30)

As amended by the CMEA, the Controlled Substances Act requires regulated sellers of SLCP's to maintain a written or electronic list of sales of SLCP's that identifies the products by name, the quantity sold, the names and addresses of purchasers, and the dates and times of the sales for all transactions covered by the CMEA, except for sales of single doses of 60 mg or less of pseudoephedrine. 21 USC 830(e)(1)(A)(iii). The CMEA refers to the list as a logbook.

1. Bound Logbooks

Perhaps the most troublesome aspect of the CMEA interim final rules is contained in 21 CFR 1314.30(a)(2), which requires retailers who choose the statutorily permitted option of paper logbooks create and maintain this information in a bound record book. The requirement exceeds the scope of the statute, places an undue and unnecessary burden on regulated sellers, and is not supported by any evidence that a bound logbook will in any way advance the goals of the CMEA.

First, the CMEA, which is specific in many ways, is silent with respect to the format of the logbook. The CMEA states that the logbook may be maintained on paper or in electronic form, but does not provide any further specifications regarding the shape or form of the logbook. Therefore, the interim regulatory requirement that paper logbooks be maintained in bound form is beyond the scope of the statute.

Second, DEA does not provide any support or rationale in the preamble for the imposition of this requirement. The Agency states that sales records for Schedule V controlled substances sold without a prescription must also be maintained in a bound logbook and then continues by stating that "bound blank logbooks and ledger books meeting DEA's regulatory requirements are readily available on the commercial market." 71 Fed. Reg. at 56011. DEA officials have explained in discussions about the rule that traditional academic composition books or similar notebooks would meet the regulatory requirement. However, while these items are clearly bound, it would be virtually impossible for retailers to standardize the use of composition books across hundreds or thousands of stores. Each page

would need to be individually drawn into columns and rows to facilitate the entry of the name, address, sales, and product information that the CMEA requires be entered for every transaction. The warning statement discussed below would have to be embossed on each individual logbook. Clearly, this approach is inefficient and burdensome.

Third, DEA provides no explanation in the preamble as to how bound logbooks will advance the purposes of the CMEA. In discussions about the requirement, DEA has stated that bound logbooks will provide evidence of tampering, however, DEA, again, provides no evidence as to why tamper-evident logbooks are important in the effort to thwart illicit use of methamphetamine precursors. If DEA is seeking tamper-evident logbooks, the Agency should replace the requirement in the interim final rule that the logbooks be bound with a requirement that regulated sellers use tamper-evident logbooks. Logbooks may be rendered tamper-evident in any number of ways, including numbering the individual pages.

The bound logbook requirement in the interim final rule is cumbersome at best. In the absence of any statutory requirement for bound logbooks, DEA should not require anything of the sort. Nonetheless, if the Agency has a sound and statutorily sufficient basis to require tamper-evident logbooks, the final rules should be amended to allow retailers to use any logbook format that would allow the Agency to identify if tampering had occurred.

2. Federal/State

As discussed more fully below, the CMEA does not preempt state laws that have requirements related to the sale of SLCP's that are in addition to or more stringent than the federal law. Indeed, many states also require the maintenance of logbooks although some states require the inclusion of information not required under the federal law. In those cases, regulated sellers should be allowed to maintain a single logbook that includes all of the necessary federal and state information, rather than maintaining two separate logbooks. DEA should expressly recognize the legality of this approach in the final rules.

3. Electronic/Manual

The CMEA expressly permits regulated sellers to maintain a logbook of SLCP transactions in either written or electronic form. The statutory provision gives retailers a broad degree of flexibility in how the logbooks are maintained and we urge DEA to codify this flexibility in the regulations.

Specifically, retailers may need to keep both electronic and manual logbooks and such should be allowed. For example, a retailer with an electronic recordkeeping system may experience periodic technical malfunctions. Alternately, a retailer who customarily uses an electronic logbook system but also delivers medications, including SLCP's to customers, may need to transport a written logbook with the medication. In these circumstances and others, the regulated seller should be allowed to satisfy the logbook requirement using either a written or electronic logbook.

In addition, although not expressly authorized by the CMEA, we urge DEA to exercise discretion and allow regulated sellers to use a combination of electronic and written media to meet the logbook requirement for twelve months following promulgation of the final rules. Many retailers would prefer to use an electronic format and are actively developing such systems, however, programming and store level implementation are time-consuming. Given the very short window between issuance of the interim final rule and the compliance period, some retailers have needed to triage together a combination of logbook approaches in order to continue selling SLCP's. Although we recognize that the CMEA requires the maintenance of a written *or* electronic list, we urge DEA to allow retailers to use both for a limited time, provided, of course, that the retailer assumes the risks of any missing information that may result from the interim use of a combination electronic/manual logbook.

4. Entry of Information

The CMEA is unusually specific about the responsibilities of both the regulated seller and the prospective SLCP purchaser for entering information into the logbooks. In this regard, the CMEA requires the purchaser to enter his or her name, address, date and time of sale, and to sign the logbook entry. The regulated seller is required to enter the name of the product and the quantity sold. 21 USC 830(e)(1)(iv).

The interim final rules codify the aforementioned division of labor and provide some welcome latitude in fulfilling these obligations, but only for those who utilize electronic logbooks. Specifically, DEA states that, if it is not feasible for the purchaser to enter the information electronically the regulated seller may ask the purchaser for the name and address and enter it, rather than simply copying the information from the required photo identification (discussed below). 21 CFR 1314.30(c). In the preamble, the Agency further explains that some purchasers may find it difficult or impossible to enter information electronically themselves. As an example, the Agency cites an electronic system that is maintained behind the pharmacy counter. 71 Fed. Reg. at 56012.

Although we appreciate the flexibility expressed in the interim final rule and the preamble, we urge DEA to recognize that there are multiple situations in which it will not be feasible for customers to enter information directly and to allow regulated sellers to assist customers in those cases, regardless of whether the logbook is maintained in electronic or written format. For example, persons with physical or mental disabilities may need assistance in entering the required information, regardless of whether the regulated seller maintains the logbook in written or electronic format. Under Title III of the Americans with Disabilities Act, places of public accommodation, such as retail stores, must provide assistance or alternative steps in order to make goods and services accessible to individuals, as long as such steps are readily achievable. Older customers or those who cannot write may need assistance completing logbooks. Similarly, caregivers or family members should be allowed to enter logbook information when necessary. Thus, DEA's final regulations should clearly state that store personnel, caregivers or family members may assist purchasers by completing logbook entries whenever it is not feasible for the purchaser to enter information

directly him- or herself, regardless of whether the logbook is maintained in paper or electronic form.

5. False Statements Notice

The CMEA requires the logbook to include a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchasers to criminal penalties under section 1001 of title 18 of the United States Code. The CMEA requires DEA to provide the criteria for the notice, including specifying the maximum fine and term of imprisonment under 18 USC 1001. Accordingly, the interim final rule provides the following notice that must be included in all logbooks:

> **Warning:** Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both.

21 CFR 1314.30(f).

a. Placement

The interim final rule permits the notice to be included in or displayed by the logbook. 21 CFR 1314.30(f). The preamble elaborates somewhat on this indicating that the seller may prominently display the notice where the purchaser will see it when entering or providing the information. 71 Fed. Reg. at 56012.

The Agency was correct when it indicated that retailers may have difficulty including the warning statement in the logbook itself and have identified several different alternatives. We respectfully request that DEA expressly recognize that any of the following would meet the regulatory requirement: displaying the notice under counter glass near the logbook; affixing the statement to the wall behind the logbook; or placing the statement on the cover of the logbook.

b. Coordination with State Requirements

In addition, retailers in some states are faced with multiple warning requirements. For example, in North Carolina, retailers must provide the following notice with the logbook:

> North Carolina law strictly prohibits the purchase of more than two packages of certain products containing pseudoephedrine (3.6 grams total) per day, and more than three packages (9 grams total) of certain products containing pseudoephedrine within a 30-day period. By my signature, I attest that the information I have provided in

> connection with this transaction is true and correct and that this transaction does not exceed the purchase restrictions. I acknowledge that knowing and willful violation of the purchase restrictions or the furnishing of false information in connection therewith may subject me to criminal penalties.

Section 90-113.52(c), NC General Statutes. In some cases, DEA should concede that the state notice is sufficient to satisfy the federal warning requirement. Providing multiple notices is unnecessarily confusing to consumers and, quite frankly, they are unlikely to absorb all of the nuances of each. Therefore, retailers should be able to use a state-mandated warning statement in lieu of the federally required statement.

C. Photo Identification Requirements (21 CFR Section 1314.30(d))

In conjunction with the logbook requirement discussed above, purchasers of SLCP's are required to present identification to the regulated seller at the time of the transaction. Specifically, consumers may show a photo identification card issued by a State or the Federal government, or a document identified in specific sections of Title 8 the Code of Federal Regulations.[5] 21 USC 830(e)(1)(A)(iv)(I)(*aa*), citing 8 CFR 274a.2(b)(1)(v)(A) and (B). In addition, after the purchaser enters the required information discussed above in the logbook, the CMEA requires the regulated seller to "determine that the name entered in the logbook corresponds to the name provided on the identification and that the date and time entered are correct." 21 USC 830(e)(1)(A)(iv)(II)(*aa*). The interim final rule recites the statutory requirement without further guidance. 21 CFR 1314.30(d).

Our members are concerned about the practical application of this requirement at store level and urge DEA to continue to interpret the provision strictly. Specifically, the CMEA very carefully requires the regulated seller only to determine whether the name, date and time entered in the logbook are correct, but places no further obligations – such as refusing to sell the product – on the retailer. We are concerned that if DEA imposes any further restrictions beyond the scope of the statute, such restrictions will pose challenges for, and perhaps danger to, store level employees.

For example, if a law-abiding citizen has recently had a change of address or name that is not yet reflected on his or her identification, the citizen should not be refused cold medications and, indeed, the statute does not require the retailer to refuse to sell the product to the person under those circumstances. Similarly, and perhaps more disturbingly, if someone who is clearly under the influence of narcotics attempts to purchase products with a false identification, it might behoove the store clerk to capture the information presented, but refusing to sell the product to the purchaser could place the store clerk in danger.

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[5] DEA spells out the complete list of acceptable forms of identification in the preamble to the interim final rule. 71 Fed. Reg. at 56012. To assist in compliance, however, we urge DEA to reproduce the list of acceptable forms of identification in the text of the final rules themselves. Many members of the public are not well-versed enough in regulatory procedure to understand how to cross-reference to additional titles and sections of the Code of Federal Regulations. A member of the public who looks up DEA's regulations should be able to find all of the necessary requirements in one place.

Accordingly, we believe that DEA quite properly reflected the statutory standard and urge the Agency not to exceed the bounds in the final rule.

D. Training of Sales Personnel (21 CFR Section 1314.35)

The CMEA requires two types of individuals who work at store level to undergo training on the requirements of the statute. Specifically, both individuals who are responsible for delivering the products into the custody of purchasers and individuals who obtain payment for the product from consumers are required to undergo training. 21 USC 830(e)(1)(A)(vii).

1. Personnel Requirements

The CMEA requires regulated sellers to maintain records demonstrating that the necessary individuals have undergone training. 21 USC 830(e)(1)(A)(viii). The interim final rule expands the statutory requirement by requiring the regulated seller to maintain *all* records demonstrating that individuals have undergone the training. 21 CFR 1314.35(b) (emphasis added). The preamble to the interim final rule expands the statutory requirement even further by stating that store personnel who have undergone training "must" sign an acknowledgement of training received prior to selling SLCP's and then requiring the regulated seller to maintain the acknowledgement in the employee's personnel file. 71 Fed. Reg. at 56013.

The final rule should be scaled back to reflect the actual statutory requirements. Although a signed employee acknowledgement that is maintained in the employee's personnel file may be prudent measures for a retailer to take, they should not be required by the regulation itself. We recommend that DEA use the preamble to encourage retailers to take these steps but in a modified fashion. Specifically, if retailers choose to ask employees to sign an acknowledgement, the regulated seller should have the option of using either a written or electronic format. Furthermore, the regulated seller should be entitled to maintain the record wherever will best facilitate the retailer's compliance efforts, which may not be in the individual's personnel file (regardless of whether that file is maintained in written or electronic format).

2. DEA Training Program

DEA codified the training requirement in Section 1314.35 and also published a training program that is available on the DEA website.[6] Although we appreciate the training program that DEA assembled, we respectfully urge the Agency to amend the program in the following ways.

First, the DEA training program assumes that all persons who take the training will be responsible for all of the store operations that must be satisfied for a sale to occur.

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[6] See, http://www.deadiversion.usdoj.gov/meth/index.html.

Specifically and as discussed more fully above, the sales clerk who hands the product to the consumer must ensure that the consumer fills out certain portions of the logbook and must also check a photo identification provided by the consumer to the sales clerk. In some cases, this sales clerk will also accept payment for the product, however, in other retail locations, payment will be accepted by a front end cashier who has not also handed the product to the consumer. Under the latter set of circumstances, the front end cashier will not be required to complete the logbook or to check the consumer's photo identification. The current training does not differentiate between the potential functions and tells all trainees that they will be responsible for all elements of the transaction. This approach is confusing for employees of retailers who divide the responsibility between two different types of employees. Accordingly, we recommend that DEA include the following statement before the discussion of retail personnel responsibilities:

> The Combat Methamphetamine Epidemic Act requires retailers to train the following two groups of store level employees on the requirements of the Act:
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> (1) Employees who are responsible for retrieving Scheduled Listed Chemical Products from behind a counter or locked cabinet and handing the products to purchasers; and
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> (2) Employees who deal directly with purchasers by obtaining payments for the products.
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> In some stores, both functions will be performed by one employee; in others, one employee will hand products to consumers and a different employee, such as a front end cashier, will obtain payment. The following requirements apply to employees who hand products to customers, not to employees who only obtain payment.

Second, the DEA training materials improperly imply both that the retailer has an obligation to check the logbook to ensure that the daily sales limit is not exceeded and that the retailer has an obligation to police the 30 day *purchase* limitation. As the CMEA does not impose either of these obligations on retailers, we respectfully request that DEA amend the training program as follows. Slide 12, which is titled, "How much of these drug products can I sell to each customer per day?" should be amended by adding the following statement at the end:

> "You are not, however, required to consult the logbook to determine whether a transaction meets or exceeds the daily sales limit."

If the Agency insists on including Slide 15, entitled, "How much of these drug products can my customer buy in a 30-day period?," despite the fact that the retail employee has no obligation to police this limit," the Agency should add the following to the end:

> "You are not, however, required to enforce this limit; federal authorities have this responsibility."

Third, although we understand that the CMEA expressly refers to phenylpropanolamine (PPA), we have been advised by our members that the obligation to

include PPA in the training confuses the trainees because, as DEA is well-aware, PPA is not used in any over-the-counter medications, but only for prescription veterinary drugs. Accordingly, although the statute includes PPA, retail personnel will never encounter a situation where a PPA-based medication will be subject to the CMEA requirements. Therefore, we respectfully request that DEA remove the references to PPA in the training materials.

E. Self-Certification (Section 1314.40)

The CMEA requires retailers to submit a self-certification to DEA declaring that the retailer has trained all necessary employees (i.e., those who either deliver the product to consumers or who receive payment from consumers who are purchasing SLCP's) as a prerequisite to being able to sell SLCP's.

1. Frequency of Self-Certification

The CMEA is silent with respect to the frequency with which retailers must submit self-certifications to DEA after the initial self-certification. DEA's interim final rule states that retailers will be assigned an expiration date of between 12 and 23 months following the initial certification and, thereafter, the retailer will be required to certify annually. Section 1314.40(b).

We believe that this is a reasonable approach and encourage DEA to adopt an annual certification period in the final rules.[7] We urge one further refinement, however. Specifically, some companies with multiple retail locations certified each location individually (even if they were eligible to use the bulk certification format permitted for companies with ten or more retail locations). Companies that chose to certify locations individually may be faced with having to re-certify different stores within their corporate family every month going forward. Therefore, we encourage DEA to permit companies with multiple stores to choose a single re-certification date for all of their stores, provided that the date is one that DEA randomly assigned to one of the stores. Allowing stores to "bundle" their self-certifications in the future will be more efficient.

2. Signatory

The interim final rules require the self-certification to include a statement that the regulated seller understands each of the requirements that apply under this part and agrees to

[7] In the preamble, DEA suggests and dismisses the idea that retailers could be required to re-certify each time a new employee is trained at each retail location. 71 Fed. Reg. at 56013. We agree that this approach is impractical and unnecessary for the following reasons. First, it is not required by the CMEA, which only requires that retailers certify that all necessary employees are trained. If the retailer continues to ensure that all covered employees are trained, the original certification is sufficient. Second, neither DEA nor the retail store needs the volume of paperwork that would be generated by certifying with each new trainee. Employee turnover in retail locations is legendary with the average tenure of employment being less than one year. If DEA were to require a certification each time a new employee had been trained, both the Agency and the retailer would be deluged with unnecessary paperwork.

comply with the requirements, but does not specify who must sign on behalf of the company. Section 1314.40(a). The preamble requests comments on the person who should sign on behalf of the company and indicates the Agency's expectation that the signatory will e in a position to know that all employees who require training have been trained and that the retail outlet is complying with all other requirements. DEA further expects that the self-certification signatory would be authorized to sign documents for the regulated seller. 71 Fed. Reg. at 56013. In contrast, the form that DEA has posted on the website for self-certification requires the signatory to be "signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or entity." See, http://www.deadiversion.usdoj.gov/webforms/jsp/cmea/actions/register.do

DEA should simply require that the signatory be in a position to understand the requirements and to know whether the retail store location at issue is in compliance with them. In some cases, this person may also be an officer of the corporation, but not necessarily, particularly for very large companies with hundreds or thousands of retail locations. Accordingly, we recommend that DEA revise the web page for self-certification to reflect the requirement in the interim final rule that the signatory is a person who is in a position to certify that the particular retail store location is in compliance with the requirements.

3. Location of Self-Certification

The interim final rule is silent with respect to the location at which the self-certifications must be maintained. We encourage DEA to permit self-certifications to be maintained either at store level or at corporate headquarters. Our members believe that this flexibility will allow companies to choose the location with the greatest certainty that the self-certification will be properly maintained.

4. Method of Self-Certification

Although the interim final rules themselves are silent, the preamble to the final rule advises that DEA has developed a format that permits corporations with ten or more retail store locations to "bulk" certify all locations at one time. To facilitate such bulk certifications, DEA requires specific information on each store location to be entered into a specific electronic format, the entire package to be downloaded onto a disk or otherwise physically transferable object, and mailed to DEA.

Some of our members with ten or more locations chose this approach, but others preferred to certify their retail locations individually, either because they did not have the wherewithal to transfer the information into the requisite electronic format or because they preferred to receive the immediate electronic acknowledgement provided by the individual web-based certification approach. We respectfully urge DEA to clarify in the preamble to the final rule that companies with ten or more locations may use either approach.

5. User Fees

The preamble to the interim final rule notes that DEA will conduct a separate rulemaking through which the Agency intends to impose user fees on retailers who submit the statutorily required self-certifications to DEA as a prerequisite to selling SLCP's. 71 Fed. Reg. at 56013, et seq. Although we intend to respond fully when DEA issues its proposed regulation in this regard, we note at this time that the retail food industry is strongly opposed to the imposition of user fees in this regard. The new operational requirements are burdensome enough; law-abiding supermarkets and pharmacies who are selling legal over-the-counter medications to law-abiding citizens should not also have to pay DEA in order to file the paperwork that the government requires them to file to continue to sell these products to consumers.

F. Privacy Protections (Section 1314.45)

The CMEA includes a privacy provision that restricts the disclosure of information in logbooks to the Attorney General and to state and local law enforcement agencies. The CMEA further prohibits accessing, using or sharing information in the logbooks for any purpose other than to ensure compliance with the CMEA or to facilitate a product recall to protect public health and safety. 21 USC 830(e)(1)(C). The interim final rules codify the statutory requirement in Section 1314.45 without further clarification. We urge DEA to explain this requirement as follows in the final rule.

1. CMEA Provision

First, we urge DEA to clarify that incidental disclosure of logbook information to subsequent purchasers of SLCP's is not a prohibited "sharing" of the information within the meaning of Section 1314.45. Specifically, as required by the CMEA and the interim final rules, persons who intend to purchase SLCP's must themselves enter certain information into the logbook, such as their name and address. When they enter this information into a paper logbook, for example, it is entirely possible that they might see a previous entry or entries. Potential incidental disclosure of this nature should not be considered "sharing" within the meaning of the CMEA.

As defined in the Oxford English Dictionary, "to share" has an element of affirmative intent. "To share" is defined as to apportion among others, to give to others, or to distribute. The Concise Oxford Dictionary of Current English (3d ed.) at 1105 (1938). In this case, although a small amount of information may be available, the retailer certainly has no intention to distribute the information but is merely attempting to meet the legal requirements imposed on regulated sellers of SLCP's.

Moreover, the information in the logbook is not sensitive or confidential. People purchase OTC medications of this nature to treat a wide range of common cough, cold and allergy symptoms and there is no social stigma attached to their purchase. Indeed, unlike prescription drugs which are often delivered to consumers in a non-descript bag, OTC cough

and cold medicines are easily identifiable in their packaging so consumers who have been pulling them from shelves for decades have had no reasonable expectation of privacy with respect to these products.

Furthermore, retailers do not have any practical means to prevent subsequent purchasers from perhaps seeing the names of previous purchasers in a bound logbook. A separate page for each purchaser would result in enormous logbooks, particularly during the cold and flu season. A blank page to shield the names of previous purchasers would be unwieldy and probably ineffective. Given Congress's failure to require something of this sort, the absence of a prohibition on incidental disclosure, the truly non-confidential nature of the products, and the considerable burdens that would be imposed on retailers, we urge DEA to clarify in the final rule that incidental disclosure of logbook information to other purchasers when subsequent purchasers are themselves entering in the required CMEA information is not "sharing" within the meaning of the privacy protections in the CMEA or the regulations.

2. HIPAA

Second, and similarly, DEA should state in the final rule that the logbook information that regulated sellers must collect under the CMEA is not protected health information subject to the regulatory requirements of the Health Insurance Portability and Accountability Act (HIPAA). Specifically, as you are well aware, HIPAA limits the disclosure by covered entities of individually identifiable health information (also known as protected health information). In this case, to the extent that supermarkets are not health plans, health care clearinghouses, or health care providers who are transmitting health information in electronic form in connection with transactions for which the Secretary of Health and Human Services has established HIPAA standards, they are also not "covered entities" to whom the HIPAA standards apply. Furthermore, the logbook information that is collected should not be considered "protected health information" because it is not specific to an individual's medical condition (as noted above, these medications are used to treat a broad range of ailments and conditions), or the provision of health care to an individual or the individual's payment for that health care.

Moreover, HIPAA expressly permits the disclosure of information incidental to a permitted use or disclosure of information. That is, HIPAA does not require that every risk of an incidental use or disclosure of protected health information be entirely eliminated. A use or disclosure of protected health information that occurs as a result of a permitted use is acceptable under HIPAA, provided that appropriate safeguards have been implemented. In this case, the fact that only a small number of purchasers will be identified on any one page would be an appropriate safeguard. Accordingly, DEA should affirmatively state that regulated sellers may maintain the requisite CMEA logbook information and that such logbook and its use within the parameters of the CMEA is not subject to HIPAA.

G. Relationship to State Laws

The CMEA does not preempt state laws that limit or control the sale of SLCP's. 21 USC 830(g). Thus, retailers in many jurisdictions are comparing the individual requirements of their state laws with those of the federal law to determine which is more stringent. To assist the regulated community, we recommend that DEA issue a state-by-state analysis as part of its final rule to provide guidance to regulated sellers as to which provisions retailers must follow in each state. A compliance tool of this nature will assist all members of the regulated community meet their obligations and increase compliance levels.

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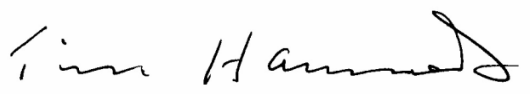
We appreciate the opportunity to provide the foregoing comments to DEA and we urge the Agency to incorporate the comments discussed above in the final rules. If you have any questions regarding our comments, please do not hesitate to contact me or Deborah White at 202 220 0614.

Sincerely,



Tim Hammonds
President and CEO

Cc: Mark Caverly, Chief, Liason and Policy Section,
Drug Enforcement Administration

Brian V. McCormack, Special Assistant to the President
and Deputy Directory of Public Liaison